DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 412, 413, 416, 419, 482, and 489

[CMS-1504-P]

RIN 0938-AP82

Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Proposed Changes to Payments to Hospitals for Certain Inpatient Hospital Services and for Graduate Medical Education Costs; and Proposed Changes to Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) to implement applicable statutory requirements and changes arising from our continuing experience with this system and to implement certain provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (Affordable Care Act). 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 prospective payment system. These proposed changes would be applicable to services furnished on or after January 1, 2011.

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 and to implement certain provisions of the Affordable Care Act. In this proposed rule, we set forth the proposed applicable relative payment weights and amounts for services furnished in ASCs, specific HCPCS codes to which these proposed changes would apply, and other pertinent ratesetting information for the CY 2011 ASC payment system. These proposed changes would be applicable to services furnished on or after January 1, 2011.

This proposed rule also includes proposals to implement provisions of the Affordable Care Act relating to payments to hospitals for direct graduate medical education (GME) and indirect medical education (IME) costs; and new limitations on certain physician referrals to hospitals in which they have an ownership or investment interest.

DATES: 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 August 31, 2010.

ADDRESSES: In commenting, please refer to file code CMS-1504-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 submit electronic comments on this regulation to http://www.regulations.gov**.** Follow the instructions under the "More Search Options" tab.

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Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1504-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.

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Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1504-P,

Mail Stop C4-26-05,

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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.

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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, see the beginning of the "**SUPPLEMENTARY INFORMATION**" section.

FOR FURTHER INFORMATION, CONTACT:

Alberta Dwivedi, (410) 786-0378, Hospital outpatient prospective payment issues.

Paula Smith, (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 quality data issues.

Tzvi Hefter, (410) 786-4487) and Ing-Jye Cheng, (410) 786-4548, Hospital preadmission services and direct graduate medical education and indirect medical education payments issues.

Jacqueline Proctor, (410) 786-8852, Physician ownership and investment in hospitals issues.

SUPPLEMENTARY INFORMATION:

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Alphabetical List of Acronyms Appearing in This Proposed Rule

ACEP	American College of Emergency Physicians
AHA	American Hospital Association
AHIMA	American Health Information Management Association
AMA	American Medical Association
AMP	Average manufacturer price

AOA	American Osteopathic Association
APC	Ambulatory payment classification
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
BCA	Blue Cross Association
BCBSA	Blue Cross and Blue Shield Association
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106-554
CAH	Critical access hospital
CAP	Competitive Acquisition Program
CBSA	Core-Based Statistical Area
CCR	Cost-to-charge ratio
CERT	Comprehensive Error Rate Testing
CMHC	Community mental health center
CMS	Centers for Medicare & Medicaid Services
CoP	Conditions of Participation
CORF	Comprehensive outpatient rehabilitation facility

CPT	[Physicians'] Current Procedural Terminology, Fourth Edition, 2009, copyrighted by the American Medical Association
CY	Calendar year
DMEPOS	Durable medical equipment, prosthetics, orthotics, and supplies
DMERC	Durable medical equipment regional carrier
DRA	Deficit Reduction Act of 2005, Pub. L. 109-171
DSH	Disproportionate share hospital
EACH	Essential Access Community Hospital
E/M	Evaluation and management
EPO	Erythropoietin
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
FTE	Full-time equivalent
FY	Federal fiscal year
GAO	Government Accountability Office
GME	Graduate medical education
HCERA	Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152
HCPCS	Healthcare Common Procedure Coding System

HCRIS	Hospital Cost Report Information System
HHA	Home health agency
HIPAA	Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191
HOPD	Hospital outpatient department
HOP QDRP	Hospital Outpatient Quality Data Reporting Program
ICD-9-CM	International Classification of Diseases, Ninth Edition, Clinical Modification
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
ICD-10-PCS	International Classification of Diseases, Tenth Revision, Procedure Coding System
IDE	Investigational device exemption
IHS	Indian Health Service
IME	Indirect medical education
I/OCE	Integrated Outpatient Code Editor
IOL	Intraocular lens
IPPE	Initial preventive physical examination
IPPS	[Hospital] Inpatient prospective payment system
IVIG	Intravenous immune globulin
MAC	Medicare Administrative Contractor
MedPAC	Medicare Payment Advisory Commission

MDH	Medicare-dependent, small rural hospital
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
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
NCD	National Coverage Determination
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
PHP	Partial hospitalization program
PM	Program memorandum
PPACA	Patient Protection and Affordable Care Act, Pub. L. 111-148
PPI	Producer Price Index
PPPS	Personalized preventive plan services

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
RHQDAPU	Reporting Hospital Quality Data for Annual Payment Update [Program]
RHHI	Regional home health intermediary
SBA	Small Business Administration
SCH	Sole community hospital
SDP	Single Drug Pricer
SI	Status indicator
TEFRA	Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248
TOPS	Transitional outpatient payments
USPDI	United States Pharmacopoeia Drug Information
USPSTF	United States Preventive Services Task Force
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 revised ambulatory surgical center (ASC) payment system. In addition, we are addressing provisions of the Affordable Care Act, relating to payments to hospitals for direct graduate medical

education (GME) and indirect medical education (IME) costs; we are also addressing provisions relating to new limitations on certain physician referrals to hospitals in which they have an ownership or investment interest and proposing related changes to provider agreement regulations. The provisions relating to the OPPS are included in sections I. through XIV., XVI, and XIX. through XXII. of this proposed rule and in Addenda A, B, C (Addendum C is available on the Internet only; we refer readers to section XIX.A. of this proposed rule), D1, D2, E, L, and M to this proposed rule. The provisions related to the revised ASC payment system are included in sections XV., XVI., and XIX. through XXII. of this proposed rule and in Addenda AA, BB, DD1, DD2, and EE to this proposed rule. (Addendum EE is available on the Internet only; we refer readers to section XIX.B. of this proposed rule.) The provisions related to payments to hospitals for direct graduate medical education (GME) and indirect medical education (IME) costs are included in section XVII. of this proposed rule. The provisions relating to the new limitations on certain physician referrals to hospitals in which they have an ownership or investment interest and proposed related changes to provider agreement regulations are included in section XVIII. of this proposed rule.

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I. Background and Summary of the CY 2011 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 (BBA) of 1997 (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 (BBRA) of 1999 (Pub. L. 106-113) made major changes in the hospital outpatient prospective payment system (OPPS). The following Acts made additional changes to the OPPS: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106-554); the Medicare Prescription Drug, Improvement, and

Modernization Act (MMA) of 2003 (Pub. L. 108-173); the Deficit Reduction Act (DRA) of 2005 (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 (MIEA-TRHCA) of 2006 (Pub. L. 109-432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act (MMSEA) of 2007 (Pub. L. 110-173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 (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. We refer readers to section I.D. of this proposed rule for a summary of the provisions of Pub. L. 111-148, as amended by Pub. L. 111-152, that we are proposing to implement in this proposed rule.

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) codes (which include certain Current Procedural Terminology (CPT) codes) and descriptors 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)(ii) 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 diagnostic 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 §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 2010 OPPS/ASC final

rule with comment period appears in the November 20, 2009 Federal Register (74 FR 60316). 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 2010 OPPS on the basis of claims data from January 1, 2008, through December 31, 2008, and to implement certain provisions of Pub. L. 110-173 and Pub. L. 110-275. In addition, we responded to public comments received on the provisions of the November 18, 2008 final rule with comment period (73 FR 68502) 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 July 20, 2009 OPPS/ASC proposed rule for CY 2010 (74 FR 35232).

D. Provisions of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as Amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152)

On March 23, 2010, the Patient Protection and Affordable Care Act, Pub. L. 111-148, was enacted. Following the enactment of Pub. L. 111-148, the Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152 (enacted on March 30, 2010), amended certain provisions of Pub. L. 111-148. (These two public laws are collectively known as the Affordable Care Act.) A number of the provisions of the Affordable Care Act affect the OPPS and the ASC payment system and the providers and suppliers addressed in this proposed rule. Listed below are the provisions of the Affordable Care Act that we are proposing to implement in this proposed rule. We note that, due to the timing of the passage of the legislation, we were unable to address some of the provisions

of the Affordable Care Act that affect the IPPS and the LTCH PPS in the FY 2011 IPPS/LTCH PPS proposed rule published in the **Federal Register** on May 4, 2010. Therefore, we also are including some proposals to implement certain provisions relating to the IPPS and LTCH PPS in this proposed rule. In addition, we note that we have issued or plan to issue separate documents in the **Federal Register** addressing other provisions of the Affordable Care Act (75 FR 30756 and 75 FR 31118).

- Section 1301 of the Affordable Care Act amended sections 1861(ff)(3))(A) and (B) of the Act to establish new additional requirements for CMHCs applicable to items or services furnished to Medicare beneficiaries on or after the first day of the first calendar quarter that begins at least 12 months after the date of enactment of Pub. L. 111-152 (that is, beginning April 1, 2011). The new requirements specify that a CMHC provide at least 40 percent of its services to individuals who are not eligible for Medicare benefits under Title XVIII of the Act and that a partial hospitalization program must be a distinct and organized intensive ambulatory treatment service offering less than 24-hour daily care "other than an individual's home or in an inpatient or residential setting." This provision is addressed in section X. of this proposed rule.

- Section 3121(a) of the Affordable Care Act amended section 1833(t)(7)(D)(i) of the Act to extend hold harmless payment adjustments (called transitional corridor payments or transitional outpatient payments (TOPS)) to rural hospitals with 100 or fewer beds and that are not sole community hospitals for covered OPD services furnished on or after January 1, 2006 and before January 1, 2011. Section 3121(b) amended section 1833(t)(7)(D)(i)(III) of the Act to provide that, for SCHs, in the case of covered OPD

services furnished on or after January 1, 2010, and before January 1, 2011, the hold harmless TOPS provisions shall be applied without regard to the 100-bed limitation. These provisions are addressed in section II.E. of this proposed rule.

- Section 3138 of the Affordable Care Act amended section 1833(t) of the Act to direct the Secretary to conduct a study to determine if costs incurred by cancer hospitals (described in section 1886(d)(1)(B)(v) of the Act) for outpatient hospital services with respect to APC groups exceed those costs incurred by other hospitals furnishing these services. In so far as the Secretary determines that such costs exceed those costs incurred by other hospitals, the Secretary shall provide for an appropriate adjustment under the authority of section 1833(t)(2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011. This provision is addressed in section II.F. of this proposed rule.

- Section 3401(i) of the Affordable Care Act amended section 1833(t)(3) of the Act by, among other things, adding new paragraphs (C)(iv)(F) and (G) to reduce the OPD fee schedule increase factor by a productivity adjustment and an additional adjustment for payments to hospital OPDs beginning in various years from CY 2010 through CY 2019 as applicable. These hospital OPD provisions are addressed in section II.B.1. of this proposed rule. Section 3401(k) of the Affordable Care Act amended section 1833(i)(2)(D) of the Act by adding a new subsection (iv) to provide for a similar productivity adjustment for payment for ASC services. This ASC provision is addressed in section XV.H.2.b. of this proposed rule.

- Section 4103(a) of the Affordable Care Act amended section 1861(s)(2) of the Act by adding a new subsection (FF) to provide Medicare coverage of "personalized prevention plan services," beginning January 1, 2011. Section 4103(b) of the Affordable Care Act amended section 1861 of the Act by adding a new subsection (hhh) to define "personalized prevention plan services" (also cited as the "annual wellness visit"). Section 4103(c) of the Affordable Care Act excludes the annual wellness visit from payment under the OPPS and provides for the elimination of beneficiary coinsurance requirements for these preventive services in outpatient hospital settings and for waiver of application of the deductible for these services. These provisions are addressed in section XII.B. of this proposed rule.

- Section 4104(a) of the Affordable Care Act amended section 1861(ddd) of the Act to define "preventive services" under Medicare to include screening and preventive services described under subsection (ww)(2) of the Act (other than services under subparagraph (M)); an initial preventive physical examination as defined in subsection (ww) of the Act; and personalized prevention plan services as defined in subsection (hhh)(1) of the Act. Section 4104(b) of the Affordable Care Act amended section 1833(a)(1) of the Act, as amended by section 4103(c)(1) of the Affordable Care Act, to provide for the elimination of coinsurance for most preventive services, and section 4104(c) amended section 1833(b) of the Act to provide for the waiver of the application of the deductible for most preventive services and, specifically, for colorectal cancer screening tests that become diagnostic and any related services performed with that diagnostic colorectal cancer screening test performed in the same clinical encounter,

effective for items and services furnished on or after January 1, 2011. These provisions are addressed in section XII.B. of this proposed rule.

- Sections 5503, 5504, 5505, and 5506 of the Affordable Care Act made a number of changes to various sections of the Act relating to payment for direct GME and IME costs to hospitals.

(1) Section 5503 amended the Act to add a provision to redistribute medical residency positions that have been unfilled during a prior cost reporting period to other hospitals and to direct slots for training primary care physicians beginning July 1, 2011.

(2) Section 5504 amended sections 1886(h)(4)(E) and 1886(d)(5)(B)(iv) of the Act to allow any time spent by residents training in a nonprovider setting to count toward direct GME and IME costs if the hospital incurs the costs of residents' salaries and fringe benefits, effective for cost reporting periods beginning on or after July 1, 2010, for direct GME, and for discharges occurring on or after July 1, 2010, for IME.

(3) Section 5505 amended section 1886(h) and section 1886(d)(5)(B) of the Act to add a provision to allow hospitals to count resident time spent in certain non-patient care activities while training in certain nonhospital settings for direct GME purposes, effective for cost reporting periods beginning on or after July 1, 2009; to allow hospitals to count resident time spent in certain non-patient care activities while training in certain hospital settings for IME purposes for cost reporting periods beginning on or after January 1, 1983; and to prohibit the counting of time spent by residents in research not associated with the treatment or diagnosis of a particular patient for IME purposes effective October 1, 2001 (with certain limitations).

(4) Section 5506 amended section 1886(h)(4)(H) and section 1886(d)(5)(B)(iv) of the Act to add a provision to allow for the redistribution to other hospitals in the same or contiguous areas of FTE resident positions from a hospital that closes (on or after the date that is 2 years before the date of enactment of Pub. L. 111-148). These provisions are addressed in section XVII.B. of this proposed rule.

- Section 6001 of the Affordable Care Act amended section 1877 of the Act to add provisions under new subsection (i) relating to the prohibition against referrals to a hospital by a physician who has an ownership or investment interest in the hospital. This provision is addressed in section XVIII. of this proposed rule.

- Section 10324(b) of the Affordable Care Act amended section 1833(t) of the Act by adding a new subsection (19) to provide for a floor on the area wage adjustment factor for hospital outpatient department services furnished on or after January 1, 2011, in a State in which at least 50 percent of the counties in the State are frontier counties, that is, a county in which the population per square mile is less than 6. This provision is addressed in section II.C. of this proposed rule.

E. 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.E.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 four times: on November 1, 2002; on November 1, 2004; on November 21, 2006; and on November 2, 2008. 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 17 meetings, with the last meeting taking place on February 17 and 18, 2010. 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 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 Packaging Subcommittee 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. 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 2010 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 2010 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.

F. Summary of the Contents of this Proposed Rule

In this proposed rule, we set forth proposed changes to the Medicare hospital OPPS for CY 2011 to implement statutory requirements and changes arising from our continuing experience with the system and to implement certain provisions of Pub. L. 111-148, as amended by Pub. L. 111-152 (collectively known as the Affordable Care Act). In addition, we set forth proposed changes to the revised Medicare ASC payment system for CY 2011, including proposed updated payment weights, covered surgical procedures, and covered ancillary items and services based on the proposed OPPS update. We set forth proposed quality measures for the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) for reporting quality data for annual payment rate updates for CY 2012 and subsequent calendar years, the proposed requirements for data collection and submission for the annual payment update, and a proposed reduction in the OPPS payment for hospitals that fail to meet the HOP QDRP requirements for the CY 2011 payment update, in accordance with the statutory requirement. We also set forth proposed changes to implement provisions of the Affordable Care Act relating to payments to hospitals for direct GME and IME costs and the rules relating to physician

self-referrals to hospitals in which they have an ownership or investment interest. In addition, we are setting forth proposals affecting certain payments under the Medicare IPPS. The following is a summary of the major proposed changes that we are proposing to make:

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 set forth proposed 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. This proposal addresses the provisions of section 10324 of the Affordable Care Act relating to the establishment of a floor for the area wage adjustment factor for OPD services furnished in frontier States.
- 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 2011 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 2011 OPPS transitional pass-through spending for drugs, biologicals, and devices.

6. Proposed OPPS Payment for Brachytherapy Sources

In section VII. of this proposed rule, we discuss our proposal for payment for brachytherapy sources.

7. Proposed OPPS Payment for Drug Administration Services

In section VIII. of this proposed rule, we set forth our proposed policy concerning coding and payment for drug administration services.

8. Proposed OPPS Payment for Hospital Outpatient Visits

In section IX. 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.

9. Proposed Payment for Partial Hospitalization Services

In section X. of this proposed rule, we set forth our proposed payment for partial hospitalization services, including the proposed separate threshold for outlier payments for CMHCs. We also set for our proposals to implement the new requirements for CMHCs established by section 1301 of the Affordable Care Act.

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

In section XI. 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.

11. Proposed OPPS Nonrecurring Technical and Policy Changes and Clarifications

In section XII. of this proposed rule, we discuss nonrecurring technical issues and proposed policy changes relating to physician supervision of OPD services in hospitals, including CAHs. We also are proposing to implement the provisions of sections 4103 and 4104 of the Affordable Care Act relating to payment for preventive services, including personalized prevention plan services, and the waiver of beneficiary coinsurance and deductibles.

12. Proposed OPPS Payment Status and Comment Indicators

In section XIII. of this proposed rule, we discuss our proposed changes to the definitions of status indicators assigned to APCs and present our proposed comment indicators for the final rule with comment period.

13. OPPS Policy and Payment Recommendations

In section XIV. of this proposed rule, we address recommendations made by the Medicare Payment Advisory Commission (MedPAC) in its March 2010 report to Congress, by the Office of Inspector General (OIG), and by the APC Panel regarding the OPPS for CY 2011.

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

In section XV. of this proposed rule, we discuss the proposed updates of the revised ASC payment system and payment rates for CY 2011.

15. Reporting Quality Data for Annual Payment Rate Updates

In section XVI. of this proposed rule, we discuss the proposed quality measures for reporting hospital outpatient (HOP) quality data for the annual payment update factor for CY 2012 and subsequent calendar years; set forth the requirements for data collection and submission for the annual payment update; and discuss the reduction in the OPPS payment for hospitals that fail to meet the HOP Quality Data Reporting Program (QDRP) requirements for CY 2011.

16. Bundling of Payments for Inpatient and Outpatient Services and Payments to Hospitals for Direct GME and IME Costs

In section XVII. of this proposed rule, we discuss our proposed implementation of the provisions of section 5503, 5504, 5505, and 5506 of the Affordable Care Act relating to redistribution of FTE resident slots of closed hospitals and policy changes for the counting of FTE residents in determining payments to hospitals for direct GME and IME costs.

17. Physician Self-Referrals to Hospitals

In section XVIII. of this preamble, we discuss our proposal to implement the changes made by section 6001 of the Affordable Care Act relating to the rules governing the prohibition on referrals to a hospital by a physician who has an ownership or investment interest in the hospital.

18. Regulatory Impact Analysis

In section XXII. of this proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected entities and beneficiaries.

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 CY 2011, we are proposing to use the same basic methodology that we described in the November 20, 2009 OPPS final rule with comment period to recalibrate the APC relative payment weights for services furnished on or after January 1, 2011, and before January 1, 2012 (CY 2011). 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. We are proposing to use the most recent available data to construct the database for calculating APC group weights. Therefore, for the purpose of recalibrating the proposed APC relative payment weights for CY 2011, we used approximately 133 million final action claims for hospital outpatient department services furnished on or after January 1, 2009, and before January 1, 2010. (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 133 million final action claims for services provided in hospital outpatient settings used to calculate the CY 2011 OPPS payment rates for this proposed rule, approximately 102 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 102 million claims, approximately 4 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 98 million claims, we created approximately 95 million single records, of which approximately 64 million were "pseudo" single or “single session” claims (created from 24 million multiple procedure claims using the process we discuss later in this section). Approximately 696,000 claims were trimmed out on cost or units in excess of +/- 3 standard deviations from the geometric mean, yielding approximately 95 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, with the intention of using more appropriate data from the available claims. In some cases, the bypass process allows us to use some portion of the submitted claim for cost estimation purposes, while the remaining information on the claim continues to be unusable. Consistent with the goal of using appropriate information in our data development process, we only use claims (or portions of each claim) that are appropriate

for ratesetting purposes. Ultimately, we were able to use for CY 2011 ratesetting some portion of 95 percent of the CY 2009 claims containing services payable under the OPPS.

The proposed APC relative weights and payments for CY 2011 in Addenda A and B to this proposed rule were calculated using claims from CY 2009 that were processed before January 1, 2010, and continue to be based on the median hospital costs for services in the APC groups. We selected claims for services paid under the OPPS and matched 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 2011 payment rates.

b. Proposed Use of Single and Multiple Procedure Claims

For CY 2011, 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.

We agree that, optimally, it is 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 continued to use date of service stratification and a list of codes to be bypassed to convert multiple procedure claims to "pseudo" single procedure claims. Through bypassing specified codes that we believe do not have significant packaged costs, we are able to use more data from multiple procedure claims. In many cases, this enables us to create multiple "pseudo" single procedure claims from claims that were submitted as multiple procedure claims spanning multiple dates of service, or claims that contained numerous separately paid procedures reported on the same date on one claim. We refer to these newly created single procedure claims as "pseudo" single procedure claims. The history of our use of a bypass list to generate "pseudo" single procedure claims is well documented, most recently in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60324 through 60342). 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 and 2010, and we are proposing to continue them for CY 2011. This 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 CY 2010, and we are proposing to continue to create them for CY 2011. 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 2011 OPPS. This methodology enabled us to create, for this proposed rule, approximately 64 million "pseudo" single procedure claims, including multiple imaging composite "single session" bills (we refer readers to section II.A.2.e.(5) of this proposed rule for further discussion), to add to the approximately 31 million "natural" single procedure claims. For this proposed rule, "pseudo" single procedure and "single session" procedure bills represent approximately 67 percent of all single procedure bills used to calculate median costs.

For CY 2011, we are proposing to bypass 448 HCPCS codes for CY 2011 that are identified in Table 1 of this proposed rule. Since the inception of the bypass list, 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 update year's data (for CY 2011, data available for the February 2010 APC Panel meeting from CY 2009 claims processed through September 30, 2009, and CY 2008 claims data processed through June 30, 2009, used to model the payment rates for CY 2010) to determine whether it would be appropriate to propose to add additional codes to the previous year's bypass list. For CY 2011, we are proposing to continue to bypass all of the HCPCS codes on the CY 2010 OPPS bypass list. We updated HCPCS codes on the CY 2010 bypass list that were mapped to new HCPCS codes for CY 2011 ratesetting by

adding the new replacement codes and also removing the deleted codes, which are listed in Table 2. 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 2011 all HCPCS codes not on the CY 2010 bypass list that, using both CY 2010 final rule data (CY 2008 claims) and February 2010 APC Panel data (first 9 months of CY 2009 claims), met the same previously established empirical criteria for the bypass list that are summarized below. The entire list proposed for CY 2011 (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 assume 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 $50. This criterion also limits the amount of error in redistributed costs. Throughout the bypass process, we do not know the dollar value of the packaged cost that should be appropriately attributed to the other procedures on the claim. 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 noted that we would consider whether it would be appropriate to update the $50 packaged cost threshold for inflation when examining potential bypass list additions (74 FR 60328). For the CY 2011 OPPS, based on CY 2009 claims data, we are proposing 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) that we initially established in the CY 2005 OPPS final rule based on our analysis of the data (69 FR 65731), rounded to the nearest $5 increment. This calculation would lead us to a proposed packaged cost threshold for bypass list additions of $50 ($51.80 rounded to $50). We believe that applying the market basket from the year of claims data to the packaged cost threshold, rounded to the nearest $5 dollar 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 cost of inputs for hospital services has increased

compared to the cost of inputs for hospital services in the prior year. 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. The dollar threshold would not change for CY 2011 under this proposed policy, because when rounded to the nearest $5 increment after adjustment for the market basket increase, the threshold would for CY 2011 remain at $50. Therefore, we are not proposing to add any additional bypass codes for CY 2011 as a result of this proposed policy.

- 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 2011 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 Table 1 below.

Table 1 below includes the proposed list of bypass codes for CY 2011. The list of bypass codes contains codes that were reported on claims for services in CY 2009 and,

therefore, includes codes that were in effect in 2009 and used for billing but were deleted for CY 2010. We retain these deleted bypass codes on the proposed CY 2011 bypass list because these codes existed in CY 2009 and were covered OPD services in that period. Since these bypass codes were deleted for billing in CY 2010, we will not need to retain them for the CY 2010 bypass list. Keeping these deleted bypass codes on the bypass list potentially allows us to create more "pseudo" single procedure claims for ratesetting purposes. "Overlap bypass codes" that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Table 1 below. HCPCS codes that we are proposing to add for CY 2011 also are identified by asterisks (*) in the fourth column of Table 1. Table 2 contains the list of codes that we are proposing to remove from the CY 2011 bypass list because they were deleted from the HCPCS before CY 2009. None of these proposed deleted codes were "overlap bypass" codes.

TABLE 1.—PROPOSED CY 2009 BYPASS CODES FOR CREATING "PSEUDO" SINGLE PROCEDURE CLAIMS FOR CALCULATING MEDIAN COSTS FOR CY 2011 OPPS

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
11056	Trim skin lesions, 2 to 4		
11057	Trim skin lesions, over 4		
11300	Shave skin lesion		
11301	Shave skin lesion		
11719	Trim nail(s)		
11720	Debride nail, 1-5		
11721	Debride nail, 6 or more		
11954	Therapy for contour defects		
17000	Destruct premalg lesion		

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
17003	Destruct premalg les, 2-14		
23600	Treat humerus fracture		*
29220	Strapping of low back		
29530	Strapping of knee		*
31231	Nasal endoscopy, dx		
31579	Diagnostic laryngoscopy		
51798	Us urine capacity measure		
53661	Dilation of urethra		
54240	Penis study		
56820	Exam of vulva w/scope		
57150	Treat vagina infection		
57452	Exam of cervix w/scope		*
57454	Bx/curett of cervix w/scope		*
67820	Revise eyelashes		
69210	Remove impacted ear wax		
69220	Clean out mastoid cavity		
70030	X-ray eye for foreign body		
70100	X-ray exam of jaw		
70110	X-ray exam of jaw		
70120	X-ray exam of mastoids		
70130	X-ray exam of mastoids		
70140	X-ray exam of facial bones		
70150	X-ray exam of facial bones		
70160	X-ray exam of nasal bones		
70200	X-ray exam of eye sockets		
70210	X-ray exam of sinuses		
70220	X-ray exam of sinuses		
70240	X-ray exam, pituitary saddle		*
70250	X-ray exam of skull		
70260	X-ray exam of skull		
70320	Full mouth x-ray of teeth		*
70328	X-ray exam of jaw joint		
70330	X-ray exam of jaw joints		
70336	Magnetic image, jaw joint	*	
70355	Panoramic x-ray of jaws		
70360	X-ray exam of neck		

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
70370	Throat x-ray & fluoroscopy		
70371	Speech evaluation, complex		
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	*	
70544	Mr angiography head w/o dye	*	
70547	Mr angiography neck w/o dye	*	*
70551	Mri brain w/o dye	*	
71010	Chest x-ray		
71015	Chest x-ray		
71020	Chest x-ray		
71021	Chest x-ray		
71022	Chest x-ray		
71023	Chest x-ray and fluoroscopy		
71030	Chest x-ray		
71034	Chest x-ray and fluoroscopy		
71035	Chest x-ray		
71100	X-ray exam of ribs		
71101	X-ray exam of ribs/chest		
71110	X-ray exam of ribs		
71111	X-ray exam of ribs/chest		
71120	X-ray exam of breastbone		
71130	X-ray exam of breastbone		
71250	Ct thorax w/o dye	*	
72010	X-ray exam of spine		
72020	X-ray exam of spine		
72040	X-ray exam of neck spine		
72050	X-ray exam of neck spine		
72052	X-ray exam of neck spine		
72069	X-ray exam of trunk spine		
72070	X-ray exam of thoracic spine		
72072	X-ray exam of thoracic spine		
72074	X-ray exam of thoracic spine		
72080	X-ray exam of trunk spine		
72090	X-ray exam of trunk spine		

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
72100	X-ray exam of lower spine		
72110	X-ray exam of lower spine		
72114	X-ray exam of lower spine		
72120	X-ray exam of lower spine		
72125	Ct neck spine w/o dye	*	
72128	Ct chest spine w/o dye	*	
72131	Ct lumbar spine w/o dye	*	
72141	Mri neck spine w/o dye	*	
72146	Mri chest spine w/o dye	*	
72148	Mri lumbar spine w/o dye	*	
72170	X-ray exam of pelvis		
72190	X-ray exam of pelvis		
72192	Ct pelvis w/o dye	*	
72202	X-ray exam sacroiliac joints		
72220	X-ray exam of tailbone		
73000	X-ray exam of collar bone		
73010	X-ray exam of shoulder blade		
73020	X-ray exam of shoulder		
73030	X-ray exam of shoulder		
73050	X-ray exam of shoulders		
73060	X-ray exam of humerus		
73070	X-ray exam of elbow		
73080	X-ray exam of elbow		
73090	X-ray exam of forearm		
73100	X-ray exam of wrist		
73110	X-ray exam of wrist		
73120	X-ray exam of hand		
73130	X-ray exam of hand		
73140	X-ray exam of finger(s)		
73200	Ct upper extremity w/o dye	*	
73218	Mri upper extremity w/o dye	*	
73221	Mri joint upr extrem w/o dye	*	
73510	X-ray exam of hip		
73520	X-ray exam of hips		
73540	X-ray exam of pelvis & hips		
73550	X-ray exam of thigh		

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
73560	X-ray exam of knee, 1 or 2		
73562	X-ray exam of knee, 3		
73564	X-ray exam, knee, 4 or more		
73565	X-ray exam of knees		
73590	X-ray exam of lower leg		
73600	X-ray exam of ankle		
73610	X-ray exam of ankle		
73620	X-ray exam of foot		
73630	X-ray exam of foot		
73650	X-ray exam of heel		
73660	X-ray exam of toe(s)		
73700	Ct lower extremity w/o dye	*	
73718	Mri lower extremity w/o dye	*	
73721	Mri jnt of lwr extre w/o dye	*	
74000	X-ray exam of abdomen		
74010	X-ray exam of abdomen		
74020	X-ray exam of abdomen		
74022	X-ray exam series, abdomen		
74150	Ct abdomen w/o dye	*	
74210	Contrst x-ray exam of throat		
74220	Contrast x-ray, esophagus		
74230	Cine/vid x-ray, throat/esoph		
74246	Contrst x-ray uppr gi tract		
74247	Contrst x-ray uppr gi tract		
74249	Contrst x-ray uppr gi tract		
76100	X-ray exam of body section		
76510	Ophth us, b & quant a		
76511	Ophth us, quant a only		
76512	Ophth us, b w/non-quant a		
76513	Echo exam of eye, water bath		
76514	Echo exam of eye, thickness		
76516	Echo exam of eye		
76519	Echo exam of eye		
76536	Us exam of head and neck		
76645	Us exam, breast(s)		
76700	Us exam, abdom, complete	*	

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
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	*	
76801	Ob us < 14 wks, single fetus		
76805	Ob us >/= 14 wks, sngl fetus		
76811	Ob us, detailed, sngl fetus		
76816	Ob us, follow-up, per fetus		
76817	Transvaginal us, obstetric		
76830	Transvaginal us, non-ob		
76856	Us exam, pelvic, complete	*	
76857	Us exam, pelvic, limited	*	
76870	Us exam, scrotum	*	
76880	Us exam, extremity		
76970	Ultrasound exam follow-up		
76977	Us bone density measure		
77072	X-rays for bone age		
77073	X-rays, bone length studies		
77074	X-rays, bone survey, limited		
77075	X-rays, bone survey complete		
77076	X-rays, bone survey, infant		
77077	Joint survey, single view		
77078	Ct bone density, axial		
77079	Ct bone density, peripheral		
77080	Dxa bone density, axial		
77081	Dxa bone density/peripheral		
77082	Dxa bone density, vert fx		
77083	Radiographic absorptiometry		
77084	Magnetic image, bone marrow		
77300	Radiation therapy dose plan		
77301	Radiotherapy dose plan, imrt		
77315	Teletx isodose plan complex		
77327	Brachytx isodose calc interm		
77331	Special radiation dosimetry		
77336	Radiation physics consult		
77370	Radiation physics consult		

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
77401	Radiation treatment delivery		
77600	Hyperthermia treatment		
77605	Hyperthermia treatment		
77610	Hyperthermia treatment		
78350	Bone mineral, single photon		*
80500	Lab pathology consultation		
80502	Lab pathology consultation		
85097	Bone marrow interpretation		
86510	Histoplasmosis skin test		
86850	RBC antibody screen		
86870	RBC antibody identification		
86880	Coombs test, direct		
86885	Coombs test, indirect, qual		
86886	Coombs test, indirect, titer		
86890	Autologous blood process		
86900	Blood typing, ABO		
86901	Blood typing, Rh (D)		
86903	Blood typing, antigen screen		
86904	Blood typing, patient serum		
86905	Blood typing, RBC antigens		
86906	Blood typing, Rh phenotype		
86930	Frozen blood prep		
86970	RBC pretreatment		
86977	RBC pretreatment, serum		
88104	Cytopath fl nongyn, smears		
88106	Cytopath fl nongyn, filter		
88107	Cytopath fl nongyn, sm/fltr		
88108	Cytopath, concentrate tech		
88112	Cytopath, cell enhance tech		
88160	Cytopath smear, other source		
88161	Cytopath smear, other source		
88162	Cytopath smear, other source		
88172	Cytopathology eval of fna		
88173	Cytopath eval, fna, report		
88182	Cell marker study		
88184	Flowcytometry/ tc, 1 marker		

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
88185	Flowcytometry/tc, add-on		
88300	Surgical path, gross		
88302	Tissue exam by pathologist		
88304	Tissue exam by pathologist		
88305	Tissue exam by pathologist		
88307	Tissue exam by pathologist		
88311	Decalcify tissue		
88312	Special stains group 1		
88313	Special stains group 2		
88314	Histochemical stain add-on		*
88321	Microslide consultation		
88323	Microslide consultation		
88325	Comprehensive review of data		
88331	Path consult intraop, 1 bloc		
88342	Immunohistochemistry		
88346	Immunofluorescent study		
88347	Immunofluorescent study		
88348	Electron microscopy		
88358	Analysis, tumor		
88360	Tumor immunohistochem/manual		
88361	Tumor immunohistochem/comput		
88365	Insitu hybridization (fish)		
88368	Insitu hybridization, manual		
89049	Chct for mal hyperthermia		
89230	Collect sweat for test		
89240	Pathology lab procedure		
90472	Immunization admin, each add		
90474	Immune admin oral/nasal addl		
90801	Psy dx interview		
90802	Intac psy dx interview		
90804	Psytx, office, 20-30 min		
90805	Psytx, off, 20-30 min w/e&m		
90806	Psytx, off, 45-50 min		
90807	Psytx, off, 45-50 min w/e&m		
90808	Psytx, office, 75-80 min		
90809	Psytx, off, 75-80 min, w/e&m		

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
90810	Intac psytx, off, 20-30 min		
90811	Intac psytx, 20-30 min, w/e&m		
90812	Intac psytx, off, 45-50 min		
90816	Psytx, hosp, 20-30 min		
90818	Psytx, hosp, 45-50 min		
90826	Intac psytx, hosp, 45-50 min		
90845	Psychoanalysis		
90846	Family psytx w/o patient		
90847	Family psytx w/patient		
90853	Group psychotherapy		
90857	Intac group psytx		
90862	Medication management		
92002	Eye exam, new patient		
92004	Eye exam, new patient		
92012	Eye exam established pat		
92014	Eye exam & treatment		
92020	Special eye evaluation		
92025	Corneal topography		
92060	Special eye evaluation		*
92081	Visual field examination(s)		
92082	Visual field examination(s)		
92083	Visual field examination(s)		
92135	Ophth dx imaging post seg		
92136	Ophthalmic biometry		
92225	Special eye exam, initial		
92226	Special eye exam, subsequent		
92230	Eye exam with photos		
92240	Icg angiography		
92250	Eye exam with photos		
92275	Electroretinography		
92285	Eye photography		
92286	Internal eye photography		
92520	Laryngeal function studies		
92541	Spontaneous nystagmus test		
92542	Positional nystagmus test		*
92546	Sinusoidal rotational test		

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
92548	Posturography		
92552	Pure tone audiometry, air		
92553	Audiometry, air & bone		
92555	Speech threshold audiometry		
92556	Speech audiometry, complete		
92557	Comprehensive hearing test		
92567	Tympanometry		
92582	Conditioning play audiometry		
92585	Auditor evoke potent, compre		
92603	Cochlear implt f/up exam 7 >		
92604	Reprogram cochlear implt 7 >		
92626	Eval aud rehab status		
93005	Electrocardiogram, tracing		
93017	Cardiovascular stress test		
93225	ECG monitor/record, 24 hrs		
93226	ECG monitor/report, 24 hrs		
93231	Ecg monitor/record, 24 hrs		
93232	ECG monitor/report, 24 hrs		
93236	ECG monitor/report, 24 hrs		
93270	ECG recording		
93271	Ecg/monitoring and analysis		
93278	ECG/signal-averaged		
93279	Pm device progr eval, sngl		*
93280	Pm device progr eval, dual		*
93281	Pm device progr eval, multi		*
93282	Icd device progr eval, 1 sngl		*
93283	Icd device progr eval, dual		*
93284	Icd device progr eval, mult		*
93285	Ilr device eval progr		*
93288	Pm device eval in person		*
93289	Icd device interrogate		*
93290	Icm device eval		*
93291	Ilr device interrogate		*
93292	Wcd device interrogate		*
93293	Pm phone r-strip device eval		*
93296	Pm/icd remote tech serv		*

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
93306	Tte w/doppler, complete		*
93307	Tte w/o doppler, complete		*
93786	Ambulatory BP recording		
93788	Ambulatory BP analysis		
93797	Cardiac rehab		
93798	Cardiac rehab/monitor		
93875	Extracranial study		
93880	Extracranial study		
93882	Extracranial study		
93886	Intracranial study		
93888	Intracranial study		
93922	Extremity study		
93923	Extremity study		
93924	Extremity study		
93925	Lower extremity study		
93926	Lower extremity study		
93930	Upper extremity study		
93931	Upper extremity study		
93965	Extremity study		
93970	Extremity study		
93971	Extremity study		
93975	Vascular study		
93976	Vascular study		
93978	Vascular study		
93979	Vascular study		
93990	Doppler flow testing		
94015	Patient recorded spirometry		
94690	Exhaled air analysis		
95115	Immunotherapy, one injection		
95117	Immunotherapy injections		
95165	Antigen therapy services		
95250	Glucose monitoring, cont		
95805	Multiple sleep latency test		
95806	Sleep study unatt&resp efft		
95807	Sleep study, attended		
95808	Polysomnography, 1-3		

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
95812	Eeg, 41-60 minutes		
95813	Eeg, over 1 hour		
95816	Eeg, awake and drowsy		
95819	Eeg, awake and asleep		
95822	Eeg, coma or sleep only		
95869	Muscle test, thor paraspinal		
95872	Muscle test, one fiber		
95900	Motor nerve conduction test		
95921	Autonomic nerv function test		
95925	Somatosensory testing		
95926	Somatosensory testing		
95930	Visual evoked potential test		
95950	Ambulatory eeg monitoring		
95953	EEG monitoring/computer		
95970	Analyze neurostim, no prog		
95972	Analyze neurostim, complex		
95974	Cranial neurostim, complex		
95978	Analyze neurostim brain/1h		
96000	Motion analysis, video/3d		
96101	Psycho testing by psych/phys		
96111	Developmental test, extend		
96116	Neurobehavioral status exam		
96118	Neuropsych tst by psych/phys		
96119	Neuropsych testing by tec		
96150	Assess hlth/behave, init		
96151	Assess hlth/behave, subseq		
96152	Intervene hlth/behave, indiv		
96153	Intervene hlth/behave, group		
96361	Hydrate iv infusion, add-on		*
96366	Ther/proph/diag iv inf addon		*
96367	Tx/proph/dg addl seq iv inf		*
96370	Sc ther infusion, addl hr		*
96371	Sc ther infusion, reset pump		*
96375	Tx/pro/dx inj new drug addon		*
96402	Chemo hormon antineopl sq/im		
96411	Chemo, iv push, addl drug		

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
96415	Chemo, iv infusion, addl hr		
96417	Chemo iv infus each addl seq		
96423	Chemo ia infuse each addl hr		
96900	Ultraviolet light therapy		
96910	Photochemotherapy with UV-B		
96912	Photochemotherapy with UV-A		
96913	Photochemotherapy, UV-A or B		
96920	Laser tx, skin < 250 sq cm		
98925	Osteopathic manipulation		
98926	Osteopathic manipulation		
98927	Osteopathic manipulation		
98940	Chiropractic manipulation		
98941	Chiropractic manipulation		
98942	Chiropractic manipulation		
99203	Office/outpatient visit, new		*
99204	Office/outpatient visit, new		
99212	Office/outpatient visit, est		
99213	Office/outpatient visit, est		
99214	Office/outpatient visit, est		
99241	Office consultation		
99242	Office consultation		
99243	Office consultation		
99244	Office consultation		
99245	Office consultation		
99406	Behav chng smoking 3-10 min		*
99407	Behav chng smoking > 10 min		*
0144T	CT heart wo dye; qual calc		
G0008	Admin influenza virus vac		
G0101	CA screen;pelvic/breast exam		
G0127	Trim nail(s)		
G0130	Single energy x-ray study		
G0166	Extrnl counterpulse, per tx		
G0175	OPPS Service,sched team conf		
G0248	Demonstrate use home inr mon		*
G0249	Provide INR test mater/equip		*
G0340	Robt lin-radsurg fractx 2-5		

CY 2009 HCPCS Code	CY 2009 Short Descriptor	"Overlap Bypass Codes"	Proposed Additions
G0365	Vessel mapping hemo access		
G0389	Ultrasound exam AAA screen		
G0390	Trauma Respons w/hosp criti		
G0402	Initial preventive exam		*
G0404	EKG tracing for initial prev		*
M0064	Visit for drug monitoring		
Q0091	Obtaining screen pap smear		

TABLE 2.—HCPCS CODES PROPOSED TO BE REMOVED FROM THE CY 2011 BYPASS LIST BECAUSE THEY WERE DELETED PRIOR TO CY 2009

HCPCS Code	HCPCS Short Descriptor
90761	Hydrate iv infusion, add-on
90766	Ther/proph/dg iv inf, add-on
90767	Tx/proph/dg addl seq iv inf
90770	Sc ther infusion, addl hr
90771	Sc ther infusion, reset pump
90775	Tx/pro/dx inj new drug addon
93727	Analyze ilr system
93731	Analyze pacemaker system
93732	Analyze pacemaker system
93733	Telephone analy, pacemaker
93734	Analyze pacemaker system
93735	Analyze pacemaker system
93736	Telephonic analy, pacemaker
93741	Analyze ht pace device sngl
93742	Analyze ht pace device sngl
93743	Analyze ht pace device dual
93744	Analyze ht pace device dual
G0344	Initial preventive exam
G0367	EKG tracing for initial prev
G0376	Smoke/tobacco counseling >10

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

For CY 2011, 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 2011 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 2009 claims data from the most recent available hospital cost reports, in most cases, cost reports beginning in CY 2008. For the CY 2011 OPPS proposed rates, we used the set of claims processed during CY 2009. 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 2009 (the year of the claims data we are using to calculate the CY 2011 OPPS proposed payment rates). For CY 2009, there were several changes to these revenue codes. The National Uniform Billing Committee (NUBC) is the organization that is responsible for the data specifications for the Uniform Bill (currently the UB-04). For CY 2009, the NUBC changed the title of revenue code series 076X from ""Specialty Room – Treatment/Observation Room" to "Specialty Services" and changed the title of subclassification revenue code 0762 from "Observation

Room" to "Observation Hours". We are not proposing to change the revenue code-to-cost center crosswalk as a result of this change because we believe that hospitals have historically reported charges for observation based on hours of care and that this change reflects existing practices. In addition, for CY 2009, NUBC removed a note that indicated that subcategory revenue codes 0912, Behavioral Health Treatment/Services (also see 091X, an extension of 090X), and 0913, Behavioral Health Treatment/Services - Extension of 090X, were designed as zero-billed revenue codes (that is, no dollar in the amount field). This change has no impact on the revenue code-to-cost center crosswalk. We note that the addition of revenue codes with effective dates in CY 2010 is not relevant to this process because the revenue codes were not applicable to claims for services furnished during CY 2009.

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 2009 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 2007. For this proposed rule, we used the most recently submitted cost reports to calculate the CCRs to be used to calculate median costs for the proposed CY 2011 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 section II.A.1.c. of this proposed rule for all purposes that require use of an overall ancillary CCR.

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 reiterated them 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.

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 will be able to use data from the revised 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 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 Provider Reimbursement Manual–Part II, available online 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 are now available for cost reporting periods ending on or after October 1, 2009.

Furthermore, we noted in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43781 through 43782) that we were updating the cost report form to eliminate outdated requirements, in conjunction with the Paperwork Reduction Act (PRA), and that we had proposed actual changes to the cost reporting form, the attending cost reporting software, and the cost report instructions in Chapters 36 and 40 of the PRM-II. The new draft hospital cost report Form CMS-2552-10 was published in the **Federal Register** on July 2, 2009, and was subject to a 60-day review and comment period, which ended on August 31, 2009. We received numerous comments on the draft hospital cost report Form CMS-2552-10, specifically regarding the creation of new cost centers from which data might be used in the OPPS cost-based relative weights calculation. We had proposed to create new standard cost centers for Computed Tomography (CT), Magnetic Resonance Imaging (MRI), and Cardiac Catheterization in Form CMS-2552-10. If these standard cost centers are finalized, when the data become available, we would analyze the cost and charge data to determine if it is appropriate to use those data to create distinct CCRs from these cost centers in setting the relative weights. For a discussion of

these cost centers, we refer readers to the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23878 through 23880). Comments will be addressed in detail in the **Federal Register** notice that will finalize Form CMS-2552-10. The revised draft of hospital cost report Form CMS-2552-10 went on public display on April 23, 2010, and appeared in the **Federal Register** on April 30, 2010 (75 FR 22810) with a 30-day public comment period. The public comment period ended on June 1, 2010.

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 2011. 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 the CY 2011 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 2009 claims that were used to calculate the proposed payment rates for the CY 2011 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 2011 shown in Addenda A and B to this proposed rule. 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

We used the CY 2009 hospital outpatient claims processed before January 1, 2010 to calculate the median costs of APCs that underpin the proposed relative weights for CY 2011. To begin the calculation of the relative weights for CY 2011, we pulled all claims for outpatient services furnished in CY 2009 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. 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.

We divided the remaining claims into the three groups shown below. Groups 2 and 3 comprise the 102 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 .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.

At the February 17-18, 2010 APC Panel Meeting, the Panel recommended that CMS present to the Data Subcommittee an analysis of the effect of using a different lower-level threshold in the overall CCR error trim as part of the standard methodology.

The Panel members were concerned that our current CCR trimming policy (excluding providers with an overall ancillary CCR greater than 90 or less than .0001 or above and then excluding remaining providers with overall ancillary CCRs beyond +/- 3 standard deviations from the geometric mean) could result in the exclusion of claims from providers that could otherwise be used for ratesetting and modeling. We are accepting this recommendation. We will study the issue and provide the relevant data to the Data Subcommittee at an upcoming meeting.

We applied 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 (the lines stay on the claim, but are copied onto another file) to a separate 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.

To implement our proposed policy to redistribute some portion of total cost for packaged drugs and biologicals to the separately payable drugs and biologicals as acquisition and pharmacy overhead and handling costs discussed in section V.B.3. of this proposed rule, 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, 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 2010 ASP amount multiplied by total units for each drug or biological in the CY 2009 claims data). These values are ASP+14 percent (for all drugs and biologicals with HCPCS codes, whether separately paid or packaged), ASP+0 percent (for drugs and biologicals that are separately paid), and ASP+283 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 a policy to redistribute $150 million of the total cost in our claims data for packaged drugs and biologicals that have an associated ASP from packaged drugs with an ASP to separately payable drugs and biologicals. We also are proposing a policy to redistribute an additional $50 million of the total cost in our claims data for drugs and biologicals lacking an ASP, largely for estimated costs

associated with uncoded charges billed under pharmacy revenue code series 025X (Pharmacy (also see 063X, an extension of 025X)), 026X (IV Therapy), and 063X (Pharmacy – Extension of 025X). We observe about $623 million for drugs lacking an ASP in our CY 2009 claims data. 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.

Removing a total of $150 million in pharmacy overhead cost from packaged drugs and biologicals reduces the $593 million to $443 million, approximately a 25 percent reduction. Removing $50 million from the cost of drugs lacking an ASP reduces the $623 million to $573 million, approximately an 8 percent reduction. To implement our proposed CY 2011 policy to redistribute $150 million in claim cost from packaged drugs and biologicals with an ASP to separately payable drugs and biologicals and $50 million in claim cost from packaged drugs and biologicals lacking an ASP, including uncoded pharmacy revenue code charges, we multiplied the cost of each packaged drug or biological with a HCPCS code and ASP pricing information in our CY 2009 claims data by 0.75, and we multiplied all other packaged drug costs in our CY 2009 claims data, excluding those for diagnostic radiopharmaceuticals, by 0.92. We also added the redistributed $200 million to the total cost of separately payable drugs and biologicals in our CY 2009 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+0 percent to ASP+6 percent. We refer readers to section

V.B.3. of this proposed rule for a complete discussion of our proposal to pay for separately paid drugs and biologicals and pharmacy overhead for CY 2011.

We then removed line-items that were not paid during claim processing, presumably for a line-item rejection or denial. We added this process to our median cost calculation methodology for the CY 2010 OPPS, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60359). 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 for the claim year and a status indicator of "S," "T," "V," or "X" when separately paid under the prospective year's payment system. This logic preserves charges for services that would not have been paid in the claim year but for which some estimate of cost is needed for the prospective year, such as services newly proposed to come off the inpatient list for CY 2010 that were assigned status indicator "C" in the claim year.

For CY 2011, we are proposing to expand the application of this trim to exclude line-item data for pass-through drugs and biologicals (status indicator "G" for CY 2009) and nonpass-through drugs and biologicals (status indicator "K" for CY 2009) 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). For approximately 90 percent of the codes with status indicators "G" and "K" in their claims year, to which the expansion of the trim would apply, between 0 and 10 percent of lines would be removed due to receiving zero payment. As with our trimming in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60359) 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.

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 2011, 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 2011, 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 2011 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 earlier in Table 1 and discussed in section II.A.1.b. of this proposed rule to remove separately payable procedures that 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 2011 "overlap bypass codes" are listed in Table 1 in section II.A.1.b. of this proposed rule. 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 2010 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 2010 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 2010 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 selected codes 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 2010 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 2010 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 2010 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.

Lastly, where a multiple procedure minor claim contained multiple codes with status indicator “Q2” (“T-packaged”) and status indicator “Q1” (“STVX-packaged”), we selected the status indicator “Q2” HCPCS code (“T-packaged”) that had the highest relative weight for CY 2010 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 2010 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 2010 relative weights. If a status indicator “Q1” HCPCS code had a higher CY 2010 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.

In public comments received on the CY 2010 OPPS/ASC proposed rule, a public commenter suggested that CMS could use more claims data to develop medians for these conditionally packaged codes if CMS applied the “pseudo” single creation process to the conditionally packaged codes in the multiple major claims that still contained unusable data. We agree and, for this CY 2011 OPPS/ASC proposed rule, we are proposing to use the otherwise unusable multiple procedure claims data that remain after the standard pseudo single creation process is applied to them, in order to create more pseudo single procedure claims. We would do this by treating the conditionally packaged codes that do not meet the criteria for packaging as if they were separately payable major codes and applying the pseudo single process to the claims data to create single procedure claims from them if they meet the criteria for single procedure claims. Conditionally packaged codes are identified using status indicators “Q1” and “Q2,” and are described in section XIII.A.1. of this proposed rule. Using the February 2010 APC Panel data, we estimate that the impact of adding this proposed additional step to the pseudo single creation

process would result in a small increase in the number of claims usable for ratesetting in most cases, but with more significant increases of between 5 to 10 percent of claims for a few codes. For most of the codes affected by adding this proposed additional step to the "pseudo" single creation process, we found no significant changes to the APC medians. Some HCPCS codes do experience some fluctuations, with the impact of additional claims causing their APC median to decrease. We believe that this change is consistent with our goal of using more available data from within the existing set of claims information and results in a more accurate estimation of the APC median cost for conditionally packaged services.

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 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.

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 and the costs of those lines for codes with status indicator "Q1" or "Q2" when they are not separately paid), and the costs of the services reported under packaged revenue codes in Table 3 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 2011 to the revenue codes that the I/OCE will package for CY 2011 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 this CY 2011 OPPS proposed rule, we reviewed the changes to revenue codes that were effective during CY 2009 for purposes of determining the charges reported with revenue codes but without HCPCS codes that we would propose to package for the CY 2011 OPPS. As we discuss in the context of the revenue code-to-cost center crosswalk in section II.A.1.c. of this proposed rule, for CY 2009, the NUBC changed the

title of revenue code series 076x from “Specialty Room – Treatment/Observation Room” to “Specialty Services” and changed the title of subclassification revenue code 0762 from “Observation Room” to “Observation Hours”. In addition, the NUBC deleted an explanatory note following revenue code 0913, “Behavioral Health Treatment Services – Extension of 090x.” We are proposing to revise the title for revenue code 076x, Observation Hours, in Table 3 to comport to the CY 2009 revenue code title for revenue code 076x. There is no need to revise the table as a result of the deletion of the explanatory note. We believe that the charges reported under the revenue codes listed in Table 3 continue to reflect ancillary and supportive services for which hospitals report charges without HCPCS codes. Therefore, we are proposing to continue to package the costs that we derive from the charges reported under the revenue codes displayed in Table 3 below for purposes of calculating the median costs on which the CY 2011 OPPS would be based.

TABLE 3.—PROPOSED CY 2011 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

Revenue Code	Description
0271	Medical/Surgical Supplies and Devices; Non-sterile Supply
0272	Medical/Surgical Supplies and Devices; Sterile Supply
0275	Medical/Surgical Supplies and Devices; Pacemaker
0276	Medical/Surgical Supplies and Devices; Intraocular Lens
0278	Medical/Surgical Supplies and Devices; Other Implants
0279	Medical/Surgical Supplies and Devices; Other Supplies/Devices
0280	Oncology; General Classification
0289	Oncology; Other Oncology
0343	Nuclear Medicine; Diagnostic Radiopharmaceuticals
0344	Nuclear Medicine; Therapeutic Radiopharmaceuticals
0370	Anesthesia; General Classification
0371	Anesthesia; Anesthesia Incident to Radiology
0372	Anesthesia; Anesthesia Incident to Other DX Services
0379	Anesthesia; Other Anesthesia
0390	Administration, Processing and Storage for Blood and Blood Components; General Classification
0392	Administration, Processing and Storage for Blood and Blood Components; Processing and Storage
0399	Administration, Processing and Storage for Blood and Blood Components; Other Blood Handling
0621	Medical Surgical Supplies – Extension of 027X; Supplies Incident to Radiology
0622	Medical Surgical Supplies – Extension of 027X; Supplies Incident to Other DX Services
0623	Medical Supplies – Extension of 027X, Surgical Dressings
0624	Medical Surgical Supplies – Extension of 027X; FDA Investigational Devices
0630	Pharmacy – Extension of 025X; Reserved
0631	Pharmacy – Extension of 025X; Single Source Drug
0632	Pharmacy – Extension of 025X; Multiple Source Drug
0633	Pharmacy – Extension of 025X; Restrictive Prescription
0681	Trauma Response; Level I Trauma
0682	Trauma Response; Level II Trauma
0683	Trauma Response; Level III Trauma
0684	Trauma Response; Level IV Trauma
0689	Trauma Response; Other
0700	Cast Room; General Classification
0710	Recovery Room; General Classification
0720	Labor Room/Delivery; General Classification
0721	Labor Room/Delivery; Labor
0732	EKG/ECG (Electrocardiogram); Telemetry
0762	Specialty services; Observation Hours
0801	Inpatient Renal Dialysis; Inpatient Hemodialysis
0802	Inpatient Renal Dialysis; Inpatient Peritoneal Dialysis (Non-CAPD)
0803	Inpatient Renal Dialysis; Inpatient Continuous Ambulatory Peritoneal Dialysis (CAPD)
0804	Inpatient Renal Dialysis; Inpatient Continuous Cycling Peritoneal Dialysis (CCPD)

Revenue Code	Description
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 2011 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. 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 98 million claims were left. Using these 98 million claims, we created approximately 96 million single and “pseudo” single procedure claims, of which we used 95 million single bills (after trimming out approximately

696,000 claims as discussed above in this section) in the proposed CY 2011 median development and ratesetting.

We used these claims to calculate the proposed CY 2011 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). 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 X.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 X.B. of this proposed rule addresses the methodology for calculating the proposed median cost for partial hospitalization services.

At the February 2010 APC Panel Meeting, we provided the APC Panel a list of all APCs decreasing by more than 5 percent and increasing by more than 15 percent when comparing the proposed CY 2011 median costs based on data available for the February 2010 APC Panel meeting from CY 2009 claims processed through September 30, 2009, to those based on CY 2010 OPPS/ASC final rule data (CY 2008 claims). The APC Panel reviewed these fluctuations in the APC median costs but did not express particular concerns with the median cost changes.

As we stated earlier, at the February 2010 APC Panel Meeting, the APC Panel also recommended that the Data Subcommittee continue its work. We are proposing to accept that 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 2011, we are proposing to continue to use the standard methodology for calculating median costs for device-dependent APCs that was finalized in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60365). 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 2011 using only the subset of single procedure claims from CY 2009 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 "FC" modifier became effective January 1, 2008, and was present for the first time on claims that were used in OPPS ratesetting for CY 2010. We continue to believe the standard methodology for calculating median costs for device-dependent APCs gives us the most appropriate proposed median costs for device-dependent APCs in which the hospital incurs the full cost of the device.

The median costs for the majority of device-dependent APCs that are calculated using the CY 2011 proposed rule claims data are generally stable, with most median costs increasing moderately compared to the median costs upon which the CY 2010 OPPS payment rates were based. However, the median costs for APC 0225 (Implantation of

Neurostimulator Electrodes, Cranial Nerve) and APC 0418 (Insertion of Left Ventricular Pacing Electrode) demonstrate significant fluctuation. Specifically, the proposed CY 2011 median cost for APC 0225 increased approximately 40 percent compared to its final CY 2010 median cost, while the proposed CY 2011 median cost for APC 0418, which had increased approximately 53 percent from CY 2009 to CY 2010, showed a decrease of approximately 27 percent based on the claims data available for this CY 2011 proposed rule. We believe the fluctuations in median costs for these two APCs are a consequence of the small number of single bills upon which the median costs are based and the small number of providers of these services. As we have stated in the past, some fluctuation in relative costs from year to year is to be expected in a prospective payment system for low volume device-dependent APCs, particularly where there are small numbers of single bills from a small number of providers. The additional single bills available for ratesetting in the CY 2011 final rule data and updated cost report data may result in less fluctuation in the median costs for these APCs for CY 2011.

Table 4 below lists the APCs for which we are proposing to use our standard device-dependent APC ratesetting methodology for CY 2011. We refer readers to Addendum A to this proposed rule for the proposed payment rates for these APCs.

TABLE 4.—PROPOSED CY 2011 DEVICE-DEPENDENT APCs

Proposed CY 2011 APC	Proposed CY 2011 Status Indicator	Proposed CY 2011 APC Title
0039	S	Level I Implantation of Neurostimulator Generator
0040	S	Percutaneous Implantation of Neurostimulator Electrodes
0061	S	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes
0082	T	Coronary or Non-Coronary Atherectomy

Proposed CY 2011 APC	Proposed CY 2011 Status Indicator	Proposed CY 2011 APC Title
0083	T	Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty
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 Cardioverter-Defibrillator Leads
0115	T	Cannula/Access Device Procedures
0202	T	Level VII Female Reproductive Procedures
0225	S	Implantation of Neurostimulator Electrodes, Cranial Nerve
0227	T	Implantation of Drug Infusion Device
0229	T	Transcatheter Placement of Intravascular Shunts
0259	T	Level VII ENT Procedures
0293	T	Level V Anterior Segment Eye Procedures
0315	S	Level II Implantation of Neurostimulator Generator
0384	T	GI Procedures with Stents
0385	S	Level I Prosthetic Urological Procedures
0386	S	Level II Prosthetic Urological Procedures
0418	T	Insertion of Left Ventricular Pacing Electrode
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

(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 2011, 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 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 2011 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 better 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 provider, we believe that it yields more accurate estimated costs for these products. We believe that continuing with this methodology in CY 2011 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 for the proposed CY 2011 payment rates for blood and blood products, which are identified with status indicator "R." For 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) Single Allergy Tests

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 2011. Multiple allergy tests are currently assigned to APC 0370 (Allergy Tests), with a median cost calculated based on the standard OPPS methodology. 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. Our CY 2009 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 $52, significantly higher than the CY 2010 median cost of APC 0381 of approximately $29 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 are proposing to calculate a "per unit" median cost for APC 0381, based upon 595 claims containing multiple units or multiple occurrences of a single CPT code. The proposed CY 2011 median cost for APC 0381 using the "per unit" methodology is approximately $29. For a full discussion of this

methodology, 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. 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 the last 5 years. For CY 2011, 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 $109 using 328,960 claims with multiple units or multiple occurrences for HCPCS code C1300 for CY 2011.

(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/ASC final rule with comment period (71 FR 68157 through 68158).

For CY 2011, 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. 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, using estimated costs from claims data for line-items with a HCPCS code assigned to status indicators “G,” “H,” “K,” “N,” “Q1,” “Q2,” “Q3,” “R,” “S,” “T,” “U,” “V,” and “X” and charges for packaged revenue codes without a HCPCS code (we refer readers to section XIII.A.1. of this proposed rule for a complete listing of status indicators). We continue to believe that this 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. Although the median cost for APC 0375 has increased, the median in the CY 2009 OPPS claims data used for development of proposed rates for CY 2011 was only slightly higher than that for CY 2010. 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 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 5 below shows the number of claims and the final median costs for APC 0375 for CYs 2007, 2008, 2009, and 2010. For CY 2011, we are proposing a median cost of approximately $6,566 for APC 0375 based on 117 claims.

TABLE 5.--CLAIMS FOR ANCILLARY OUTPATIENT SERVICES WHEN PATIENT EXPIRES (–CA MODIFIER) FOR CYs 2007 THROUGH 2010

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

(6) Pulmonary Rehabilitation

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 (PR) services furnished as a part of the comprehensive PR program benefit (74 FR 60567). We created new HCPCS code G0424 (Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day) and assigned it to new APC 0102 (Level II Pulmonary Treatment).

For CY 2011, we are proposing to continue to require hospitals to report PR services provided under the comprehensive PR benefit in section 1861(fff) of the Act using HCPCS code G0424. We also are proposing to continue to use the methodology described in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60567 through 60570) to calculate the median cost on which the proposed payment rate for CY 2011 is based. Specifically, we are proposing to continue to assign HCPCS code G0424 to APC 0102 and to calculate a median ‘‘per session’’ cost simulated from historical hospital claims data for similar pulmonary therapy services for the CY 2011 OPPS.

To simulate the proposed “per session” median cost of 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, face to face, one on one, each 15 minutes (includes monitoring)) or G0238 (Therapeutic procedures to improve respiratory function, other than described by G0237, 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 continue to believe that patients in a PR program would typically receive individual and group services in each session of approximately 1 hour in duration. This proposal is consistent with public comments on the CY 2010 OPPS/ASC proposed rule that were addressed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60569) that suggested that PR 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 is 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 used for CY 2010 OPPS final rule ratesetting. We continue to believe that the typical session of PR is 1 hour based on public comments that indicated that a session of PR 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.

In the calculation of the proposed median cost for APC 0102, we included all costs of the related tests and assessment services, including 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, percussing, and vibration to facilitate lung function; initial demonstration and/or evaluation and all the costs of all CPT codes for established patient clinic visits) on the same date of service as the HCPCS codes in the claims we used to simulate the median cost for HCPCS code G0424, which is the only HCPCS code in APC 0102. After identifying these "per session" claims, which we believe represent 1 hour of care, we summed the costs and calculated the median cost for the set of selected claims. In light of the cost and clinical similarities of PR 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 are confident that the proposed simulated median cost for HCPCS code G0424 and APC 0102 of approximately $68 is a valid estimate of the expected hospital cost of a PR session. We note that this proposed median cost is higher than the CY 2010 final rule median cost for HCPCs code G0424 and APC 0102 of approximately $50 on which the CY 2010 payment is based.

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).

At its February 2010 meeting, the APC Panel recommended that, in order to support stem cell transplantation, CMS consider creating a composite APC or custom APC that captures the costs of stem cell acquisition performed in conjunction with recipient transplantation and preparation of tissue. We are accepting this APC Panel recommendation to consider creating a composite APC or custom APC that captures the costs of stem cell acquisition performed in conjunction with recipient transplantation and preparation of tissue, and will report the results of our assessment to the APC Panel at a future meeting.

For CY 2011, we are proposing to continue 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.

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

For CY 2011, 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 2011 median costs for these composite APCs. We are not proposing to change these criteria for the CY 2011 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 2011 OPPS.

For CY 2011, 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 2009 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 8 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 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 IX. of this proposed rule, and consistent with our CY 2008, CY 2009, and CY 2010 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 2011.

At its February 2010 meeting, the APC Panel recommended that CMS study the feasibility of expanding the extended assessment and management composite APC methodology to include services commonly furnished in conjunction with visits and observation services, such as drug infusion, electrocardiogram, and chest X-ray. We are accepting this recommendation, and we will share our assessment with the APC Panel at a future meeting.

In summary, for CY 2011, 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 and 2010. 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 2009 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 2011 median costs. The proposed CY 2011 median cost resulting from this methodology for composite APC 8002 is approximately $401, which was calculated from 17,398 single and "pseudo" single bills that met the required criteria. The proposed CY 2011 median cost for composite APC 8003 is approximately $743, which was calculated from 201,189 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 provide 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 base 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 continue 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 2011, we are proposing to continue paying for LDR prostate brachytherapy services using the composite APC methodology proposed and implemented for CYs 2008, 2009, and 2010. That is, we are proposing to use CY 2009 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 2010 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 continue to 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 2009 claims data available for this proposed rule, we were able to use 788 claims that contained both CPT codes and 55875 and 77778 to calculate the median cost upon which the proposed CY 2011 payment for composite APC 8001 is based. The proposed median cost for composite APC 8001 for CY 2011 is approximately $3,265. This is an increase compared to the CY 2010 OPPS/ASC final rule with comment period in which we calculated a final median cost for this composite APC of approximately $3,084 based on a full year of CY 2008 claims data. The proposed CY 2011 median cost for this composite APC is slightly less than $3,604, the sum of the proposed median costs for APCs 0163 and 0651 ($2,606 + $998), 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 2011 median cost for composite APC 8001 of approximately $3,265, calculated from claims we believe to be correctly coded, would result in a reasonable and appropriate payment rate for this service in CY 2011.

(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 2011, 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, CY 2009, and CY 2010. Consistent with our CY 2008 through CY 2010 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.

Using partial year CY 2009 claims data available for this proposed rule, we were able to use 8,964 claims containing a combination of group A and group B codes and calculated a proposed median cost of approximately $10,834 for composite APC 8000. This is an increase compared to the CY 2010 OPPS/ASC final rule with comment period in which we calculated a final median cost for this composite APC of approximately $10,026 based on a full year of CY 2008 claims data. We believe the proposed median cost of $10,834 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 6 below list the groups of procedures upon which we are proposing to base composite APC 8000 for CY 2011.

TABLE 6.—PROPOSED GROUPS OF CARDIAC ELECTROPHYSIOLOGIC EVALUATION AND ABLATION PROCEDURES UPON WHICH COMPOSITE APC 8000 IS BASED

Codes Used in Combinations: At Least One in Group A and One in Group B	CY 2010 CPT Code	Proposed Single Code CY 2011 APC	Proposed CY 2011 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	93620	0085	Q3

Codes Used in Combinations: At Least One in Group A and One in Group B	CY 2010 CPT Code	Proposed Single Code CY 2011 APC	Proposed CY 2011 SI (Composite)
electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording			
Group B			
Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	93650	0085	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathways, accessory atrioventricular connections or other atrial foci, singly or in combination	93651	0086	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of ventricular tachycardia	93652	0086	Q3

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

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 2011. 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 X. of this proposed rule, for CY 2011, we are proposing to use 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 set the CY 2011 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 2011 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 2010 OPPS/ASC final rule with comment period (74 FR 60403 through 60407).

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. We are accepting this recommendation and will provide the requested analysis to the APC Panel at a future meeting.

In summary, for CY 2011, 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 2011

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 2009 claims available for this proposed rule that would have 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 2010 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 8 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 70547 (Magnetic resonance angiography, neck; without contrast material(s)) to the list of bypass codes for CY 2011, we also are proposing to add CPT code 70547 to the list of proposed OPPS imaging family services overlapping with HCPCS codes on the proposed CY 2010 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."

We were able to identify 1.7 million "single session" claims out of an estimated 2.7 million potential composite cases from our ratesetting claims data, or well over half of all eligible claims, to calculate the proposed CY 2011 median costs for the multiple imaging composite APCs. Table 7 below lists the HCPCS codes that would be subject to the proposed multiple imaging composite policy and their respective families for CY 2011.

TABLE 7.—PROPOSED OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCs

Family 1 – Ultrasound	
Proposed CY 2011 APC 8004 (Ultrasound Composite)	**Proposed CY 2011 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 2011 APC 8005 (CT and CTA without Contrast Composite)*	**Proposed CY 2011 Approximate APC Median Cost = $431**
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
Proposed CY 2011 APC 8006 (CT and CTA with Contrast Composite)	**Proposed CY 2011 Approximate APC Median Cost = $649**
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
* 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 2011 APC 8007 (MRI and MRA without Contrast Composite)*	**Proposed CY 2010 Approximate APC Median Cost = $732**
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
Proposed CY 2011 APC 8008 (MRI and MRA with Contrast Composite)	**Proposed CY 2011 Approximate APC Median Cost = $1,028**
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
* 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 8.–-PROPOSED OPPS IMAGING FAMILY SERVICES OVERLAPPING WITH HCPCS CODES ON THE PROPOSED CY 2011 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
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

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 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 XIII.A.1. of this proposed rule for a complete listing of status indicators.

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 depend 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: 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 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 welcome public comments regarding our packaging proposals for calendar year (CY) 2011 OPPS.

b. Packaging Issues

(1) CMS Presentation of Findings Regarding Expanded Packaging at the February 2010 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.E. of this proposed rule, the APC Panel advises CMS on the clinical integrity of payment groups and their weights, and the APC Panel has a Packaging Subcommittee that 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/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp#TopOfPage.

During the August 5-6, 2009 meeting of the APC Panel, we agreed to continue to provide the Panel with information on the impact of increased packaging on Medicare beneficiaries building on the analyses we had presented at the February 2009 APC Panel meeting. We did not share additional packaging data with the APC Panel at the August 2009 meeting because we had already presented analysis comparing CY 2007 and CY 2008 claims data and believed the APC Panel's discussions would benefit from analyses of CY 2007 and CY 2009 claims data. We indicated that we planned to incorporate analysis of CY 2009 claims into the information we would bring to the APC Panel for its review at the winter 2010 meeting.

At the February 17-18, 2010 APC Panel meeting, we presented subsequent analyses that compared CY 2007 claims processed through September 30, 2007 to CY 2009 claims processed through September 30, 2009. Similar to the initial analysis that we presented to the APC Panel in 2009, the HCPCS codes that we compared are the ones that we identified in the CY 2008 OPPS final rule with comment period as fitting into one of the packaging categories, including HCPCS codes that became effective for CY 2009. As noted above, the seven packaging categories in our CY 2008 packaging proposal are guidance services, image processing services, intraoperative services, imaging supervision and interpretation services, diagnostic radiopharmaceuticals, contrast media, and observation services. We note that, similar to the initial analysis, we did not make any adjustments for

inflation, changes in the Medicare population, changes in payment due to APC recalibration, changes in frequency due to known changes in code definitions and coding practices, or changes in the population of hospitals paid under the OPPS. A summary of these data analyses is provided below.

Analysis of the diagnostic radiopharmaceuticals category showed that the diagnostic radiopharmaceuticals were billed 1 percent more often during the first 9 months of CY 2009 as compared to the first 9 months of CY 2007. We noticed very little change in the frequency of hospitals reporting one or more diagnostic radiopharmaceutical between CY 2007 and CY 2009. Beginning in CY 2008, we required reporting of a radiolabeled product (including diagnostic radiopharmaceuticals) when billing a nuclear medicine procedure, and we believe that the modest increases in frequency of reporting diagnostic radiopharmaceuticals and the percentage of reporting hospitals generally reflects hospitals adhering to our reporting requirements.

We also found that nuclear medicine procedures (into which diagnostic radiopharmaceuticals were packaged) and associated diagnostic radiopharmaceuticals were billed approximately 3 million times during the first 9 months of both CY 2007 and CY 2009. Further analysis revealed that we paid hospitals over $637 million for nuclear medicine procedures and diagnostic radiopharmaceuticals during the first 9 months of CY 2007, when diagnostic radiopharmaceuticals were separately payable, and approximately the same amount for nuclear medicine procedures and diagnostic radiopharmaceuticals during the first 9 months of CY 2009, when payment for diagnostic radiopharmaceuticals was packaged. This suggests that frequency and payment for

nuclear medicine procedures remained fairly steady between the first 9 months of CY 2007 and the first 9 months of CY 2009.

We conducted the same analysis for guidance services that were packaged beginning in CY 2008. Analysis of the guidance category (which includes image-guided radiation therapy services) showed that guidance services were billed 8 percent more often during CY 2009 as compared to CY 2007 and that the number of hospitals reporting guidance services declined by 1 percent between CY 2007 and CY 2009.

We also analyzed the same data for all contrast services that were packaged beginning in CY 2008. Analysis of this category showed that contrast services were billed 9 percent more often during CY 2009 as compared to CY 2007 and that the number of hospitals reporting contrast media increased by 1 percent between CY 2007 and CY 2009.

Analysis of the data for image supervision and interpretation services showed that these services were billed 10 percent more often during CY 2009 as compared to CY 2007 and, similar to guidance services and contrast agents, the number of hospitals reporting image supervision and interpretation services declined by 1 percent between CY 2007 and CY 2009.

We also analyzed the first 9 months of CY 2007 and CY 2009 data related to all image processing services that were packaged beginning in the CY 2008 OPPS. This analysis was difficult because there were significant changes to the CPT codes in this category for CY 2009. For example, the intraoperative procedures described by CPT codes 93320 (which describes spectral Doppler) and 93325 (which describes color flow

Doppler) are now reported using one comprehensive code, CPT 93306, which describes complete transthoracic echocardiogram with spectral and color flow Doppler. In an effort to isolate the effects of the changes to coding from our analysis, we removed the data for any codes experiencing significant modifications and observed a 7 percent decrease from CY 2007 to CY 2009 in the frequency of image processing services billed. However, as we pointed out to the APC panel, these numbers are not necessarily the majority of services in the category or reflective of behavioral changes for the services of interest. When we included the image processing services with the revised coding for CY 2009, the data showed a 61-percent decrease in the billing of these services between CY 2007 and CY 2009 and a 6-percent decrease in the number of hospitals reporting these services during the same timeframe.

Our analysis of changes in intraoperative services between CY 2007 and CY 2009 showed a 5-percent decrease in the billing of these services and a 5-percent decrease in the number of hospitals reporting these services during the same timeframe.

As we did for our presentation at the February 2009 APC Panel meeting, we also found that cardiac catheterization and other percutaneous vascular procedures that would typically be accompanied by Intravascular Ultrasound (IVUS), Intracardiac echocardiography (ICE), and Fractional flow reserve (FFR) (including IVUS, ICE, and FFR) were billed approximately 376,000 times in CY 2007 and approximately 473,000 times in CY 2009, representing an increase of 26 percent in the number of services and items billed between CY 2007 and CY 2009. IVUS, ICE, and FFR are intraoperative and image supervision and interpretation services that have received a lot of attention.

Further analysis showed that the OPPS paid hospitals over $912 million for cardiac catheterizations, other related services, and IVUS, ICE, and FFR in CY 2007, when IVUS, ICE, and FFR were paid separately. In the first 9 months of CY 2009, the OPPS paid hospitals approximately $1.4 billion for cardiac catheterization and other percutaneous vascular procedures and IVUS, ICE, and FFR, when payments for IVUS, ICE, and FFR were packaged. This is a 58-percent increase in payment from CY 2007. Using the first 9 months of claims data for both CY 2007 and CY 2009, we calculated an average payment per service or item provided of $2,430 in CY 2007 and $3,048 in CY 2009 for cardiac catheterization and other related services, an increase of 25 percent in average payment per item or service. This observed increase in average payment per service is most likely attributable to the observed increase in the frequency of these cardiac catheterization and other percutaneous vascular procedures that would typically be accompanied by IVUS, ICE and FFR (including IVUS, ICE, and FFR) billed in CY 2009.

We also cannot determine how much of the 58-percent increase in aggregate payment for these services may be due to the packaging of payment for IVUS, ICE, and FFR (and other services that were newly packaged for CY 2008) and how much may be due to annual APC recalibration and typical fluctuations in service frequency. However, we believe that all of these factors contributed to the notable increase in aggregate payment between CY 2007 and CY 2009.

We further analyzed the first 9 months of CY 2007 and CY 2009 claims data for radiation oncology services that would be accompanied by radiation oncology guidance.

We found that radiation oncology services (including radiation oncology guidance services) were billed approximately 4 million times in CY 2007 and 3.8 million times in CY 2009, representing a decrease in frequency of approximately 6 percent between CY 2007 and CY 2009. These numbers represented each instance where a radiation oncology service or a radiation oncology guidance service was billed. Our analysis indicated that hospitals were paid over $811 million for radiation oncology services and radiation oncology guidance services under the OPPS during the first 9 months of CY 2007, when radiation oncology guidance services were separately payable. During the first 9 months of CY 2009, when payments for radiation oncology guidance were packaged, hospitals were paid over $827 million for radiation oncology services under the OPPS. This $827 million included packaged payment for radiation oncology guidance services and represented a 2-percent increase in aggregate payment from CY 2007 to CY 2009. Using the first 9 months of claims data for both CY 2007 and CY 2009, we calculated an average payment per radiation oncology service or item billed of $199 in CY 2007 and $216 in CY 2009, representing a per service increase of 8 percent from CY 2007 to CY 2009.

At the February 2009 meeting, the APC panel also requested that CMS provide separate analyses of radiation oncology guidance, by type of radiation oncology service, specifically, intensity modulated radiation therapy (IMRT), stereotactic radiosurgery (SRS), brachytherapy, and conventional radiation therapy. The results from these analyses are discussed below:

We conducted these analyses on the specified categories using the first 9 months of claims and cost report data from CY 2007, before the expanded packaging went into effect, and the first 9 months of claims and cost report data from CY 2009—the second year of packaged payment for the radiation guidance services. We found that IMRT services were billed approximately 670 thousand times during the first 9 months of CY 2007. During this same timeframe, Medicare paid hospitals approximately $227 million for IMRT services. In comparison, during the first 9 months of CY 2009, IMRT services were billed 713 thousand times, representing an increase in frequency of 6 percent. Further, during the first 9 months of CY 2009, when payments for radiation oncology guidance were packaged into the payments for the separately paid IMRT procedures, we paid hospitals over $298 million, representing a 31-percent increase in payments from CY 2007 to CY 2009.

We further analyzed the data for SRS services and found that, for the first 9 months of CY 2007 and CY 2009, SRS services were billed approximately 9 thousand and 13 thousand times, respectively, representing an increase in frequency of 43 percent. Aggregate Medicare payments for these SRS services increased by 24 percent from $34 million in CY 2007 to $42 million in CY 2009.

Our review of the data for brachytherapy services revealed that, for the first 9 months of CY 2007 and CY 2009, these services were billed approximately 10 thousand and 11 thousand times, respectively, representing an increase in frequency of 8 percent. During this timeframe, aggregate Medicare payments for these brachytherapy

services increased by 1 percent from $9.8 million in CY 2007 to $9.9 million in CY 2009.

Our review of the data for conventional radiation therapy services revealed that conventional radiation therapy services were billed 1.4 million times and 1.1 million times, in the first 9 months of CY 2007 and CY 2009, respectively, representing a decrease in frequency of 20 percent. During this timeframe, aggregate Medicare payments for these conventional radiation services decreased by 10 percent from $189 million in CY 2007 to $169 million in CY 2009.

In reviewing our early CY 2009 claims data, which reflect the second year of packaged payment for services in the packaged categories identified in the CY 2008 OPPS/ASC final rule with comment period, we generally observed increases in the billing and reporting of packaged services described by these categories, with the caveat that we are not able to untangle the various causes of declines in the image processing category, indicating steady beneficiary access to these categories of supporting and ancillary services. In aggregate, hospitals do not appear to have significantly changed their reporting patterns as a result of the expanded packaging policy nor do the analyses suggest that hospitals have stopped offering these supporting and ancillary services with the primary diagnostic and therapeutic modalities that they support.

(2) Packaging Recommendations of the APC Panel at its February 2010 Meeting

During the February 2010 APC panel meeting, the APC Panel accepted the report of the Packaging Subcommittee, heard several presentations related to packaged services, discussed the deliberations of the Packaging Subcommittee, and made 6

recommendations. The Report of the February 2010 meeting of the APC Panel may be found at the Web site at: http://www.cms.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.

To summarize, the APC Panel made the following recommendations regarding packaging of payment under the CY 2011 OPPS:

1. That CMS consider whether CPT code 31627 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation) (also known as electromagnetic navigational bronchoscopy (ENB)) should be packaged or paid separately; if it should be paid separately, CMS should investigate the appropriate APC assignment. The Panel suggests CMS use bronchoscopic ultrasonography (EBUS) as a clinical example for comparison. (Recommendation 1)

2. That CMS make CPT code 96368 (Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion) and CPT code 96376 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular, each additional sequential intravenous push of the same substance/drug provided in the facility (List separately in addition to code for primary procedure)) separately payable in the CY 2011 OPPS/ASC final rule with comment period at an appropriate payment rate as determined by CMS. (Recommendation 2)

3. That CMS conditionally package payment for the guidance procedures that would accompany breast needle placement (specifically CPT code 19290 (Preoperative placement of needle localization wire, breast); CPT code 19291 (Preoperative placement

of needle localization wire, breast; each additional lesion (List separately in addition to code for primary procedure)); CPT code 19295 (Image guided placement, metallic localization clip, percutaneous, during breast biopsy/aspiration (List separately in addition to code for primary procedure)); CPT code 77031 (Stereotactic localization guidance for breast biopsy or needle placement (e.g., for wire localization or for injection)), each lesion, radiological supervision and interpretation); CPT code 77032 (Mammographic guidance for needle placement, breast (e.g., for wire localization or for injection), each lesion, radiological supervision and interpretation); CPT code 76942 (Ultrasonic guidance for needle placement (e.g. , biopsy, aspiration, injection, localization device), imaging supervision and interpretation)) when these guidance services are performed separately. (Recommendation 3)

4. The Panel encourages the public to submit common clinical scenarios involving currently packaged HCPCS codes and recommendations of specific services or procedures for which payment would be most appropriately packaged under the OPPS for review by the Packaging Subcommittee members. (Recommendation 4)

5. That CMS continue providing analysis on an ongoing basis of the impact on beneficiaries of the multiple imaging composite APCs as data become available. (Recommendation 5)

6. That the work of the Packaging Subcommittee continue. (Recommendation 6)

We address each of these recommendations in the discussion that follows:

Recommendation 1

At the APC Panel's February 2010 meeting, the manufacturer asserted that use of 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 argued that without separate payment for ENB, hospitals would likely not adopt the technology and the population that would likely benefit from ENB would not have access to this technology. In response to the manufacturer's assertion, the APC Panel asked CMS to consider whether CPT code 31627, which describes Electromagnetic Navigational Bronchoscopy (ENB), should be packaged or paid separately; and if it should be paid separately, the APC Panel asked CMS to investigate the appropriate APC assignment. CPT code 31627 is new for CY 2010, and we assigned it a new interim status indicator of "N" in our CY 2010 OPPS/ASC final rule with comment period based on our packaging policies (discussed in section II.A.3.a. of this proposed rule). We have considered the information available to us for CPT code 31627 and believe that the code describes a procedure that is supportive of and ancillary to the primary diagnostic or therapeutic modality, in this case, bronchoscopy procedures (for example, CPT code 31622 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed: diagnostic, with cell washing, when performed (separate procedure)). We currently package payment for CPT code 31627, and we continue to believe that this is the appropriate treatment of that code. Therefore, we are proposing to package payment for CPT code 31627. As we have discussed in past rules, in making our decision on whether to package a service or pay for it separately we consider a variety of factors,

including whether the service is normally provided separately or in conjunction with other services because it supports those services. By proposing to packaging 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. In its recommendation regarding whether to make separate payment under an APC for CPT code 31627, the APC Panel suggested that we use bronchoscopic ultrasonography as a clinical example for comparison. We consider CPT code 31620 (Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure)) to be a suitable comparison because it describes another bronchoscopic procedure in which a guidance technology (that is, ultrasonography) is used to achieve the therapeutic benefit of the procedure. Similar to our proposed payment for CPT code 31627, payment for CPT code 31620 is currently packaged into the primary modality with which it would be appropriately billed. In CY 2008, as part of our increased packaging proposal, we identified the EBUS procedure as an intraoperative ancillary service that would typically be reported in conjunction with an independent service. In addition, similar to CPT code 31627, CPT code 31620 is an add-on code that, per CPT reporting guidelines, would only be appropriately reported in conjunction with specified bronchoscopy procedures with which it would be performed. Based on these general comparisons of CPT code 31627 to the EBUS procedure described by CPT code 31620, we believe that our proposal to package payment for CPT code 31627 is consistent with the packaging approach that we have adopted in recent years. As we have stated in past rules with regard to EBUS, we

also fully expect that, to the extent these services are billed appropriately, payment for the primary service would reflect the cost of the packaged ENB procedure. For example, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68584), we discussed packaging of CPT code 31620; we state that we observed increased packaged costs associated with the services into which CPT code 31620 had been packaged, which increased the APC payment rates for bronchoscopy procedures.

In summary, we continue to believe that CPT code 31627 describes a procedure that is ancillary to and supportive of the primary service with which it is often billed. Therefore, for CY 2011, we are proposing to maintain CPT code 31627 as a packaged service.

Recommendation 2

We are not accepting the APC Panel's recommendation that CMS make CPT code 96368 and CPT code 96376 separately payable for the CY 2011 OPPS. We consider a variety of factors in making a decision whether to package a service or pay for it separately, including whether the service is normally provided separately or in conjunction with other services and 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. CPT codes 96376 and 96368 describe concurrent and sequential drug administration services that have always been packaged under the OPPS. From the inception of the OPPS through CY 2006, we paid for drug administration under the OPPS using HCPCS alphanumeric codes that packaged payment for concurrent infusions and administration of new drugs into the payment for the alphanumeric codes for drug administration. In

CY 2007, we adopted CPT codes for drug administration services. The CY 2007 CPT codes did not separately recognize administration of new drugs during the same encounter with a separate CPT code. Therefore, administration of a new drug continued to be packaged into payment for the service of which it was a part. Moreover, for CY 2007, CPT code 90768 (Intravenous infusion, for therapy, prophylaxis, or diagnosis; concurrent infusion), which was replaced by CPT code 96368, was packaged under the OPPS, continuing the longstanding practice of not making separate payment for concurrent infusion. We also pointed out that, during our implementation of this new CPT code, while it was new for CY 2007, it represented the same procedures as described by the previous drug administration HCPCS code set, and, as a result, the payment data for these procedures would be captured in the claims that were available to us for ratesetting purposes.

Similarly, CPT codes 96368 and 96376, which were created by CPT in 2008, are replacement codes for those same procedures that were described by the previous drug administration code sets and their associated data would be captured in our claims database. The costs for these services, concurrent infusion and additional push of the same drug, would continue to be packaged into payment for the drug administration codes with which they are reported. In making our decision whether to package a service or pay for it separately, we consider a variety of factors, including whether the service is normally provided separately or in conjunction with other services. CPT codes 96368 and 96376 describe concurrent and sequential drug administration services that, per CPT guidelines, are always provided in association with an initial drug administration service.

Therefore, they continue to be appropriately packaged into the payment for the separately payable services that they usually accompany. For example, CPT code 96376 would be billed with CPT code 96374 (Therapeutic, prophylactic, or diagnostic injection; intravenous push, single or initial substance/drug), which describes an initial intravenous push code and, as a result, the cost for CPT code 96376 would be reflected in the total cost for CPT code 96374. Moreover, payment for these services has always been packaged into payment for the drug administration services without which they cannot be correctly reported.

These two codes each describe services that, by definition, are always provided in conjunction with an initial drug administration code. These services have been packaged since the inception of the OPPS, and we continue to believe they are appropriately packaged into the payment for the separately payable services without which, under CPT guidelines and definitions, they cannot be appropriately reported. Therefore, for CY 2011, we are proposing to make packaged payment for CPT code 96368 and CPT code 96376 and assign them a status indicator of "N."

Recommendation 3

We are not accepting the APC Panel's recommendation that we conditionally package CPT codes 19290, 19291, 19295, 77031, 77032, and 76942. During the APC Panel's February 2010 meeting, we shared with the Packaging Subcommittee our most recent claims data for the guidance procedures that would accompany breast needle placement, demonstrating that, for some of these services, the code was billed by itself up to 25 percent of the time. While the Packaging Subcommittee broadly discussed clinical scenarios in which these services may be billed separately, it remains unclear to us why

these services are being performed separately and whether they should be paid separately. We believe that these services typically are performed in conjunction with surgical procedures involving the breast and, therefore, are appropriately packaged. Therefore, we are not accepting the APC panel's recommendation that we conditionally package payment for these guidance procedures when they are performed separately. For CY 2011, we are proposing to maintain the unconditional packaged payment status for these procedures. Specifically, we are proposing to package payment, indicated by a status indicator of "N," for CPT codes 19290, 19291, 19295, 77031, 77032, and 76942, into the primary modality with which they would be appropriately billed. However, observing such a sizable percentage of services that are the only service appearing on a claim for a packaged item, especially when these services do not receive separate payment, leads us to encourage the public to submit any clinical scenarios in their public comments involving these services that show the circumstances under which these services may be appropriately billed without a primary procedure that is furnished on the same date.

Recommendation 4

We are accepting the APC Panel's recommendation to continue to encourage submission of common clinical scenarios involving currently packaged HCPCS codes to the Packaging Subcommittee for its ongoing review. We also encourage recommendations from the public on specific services or procedures whose payment would be most appropriately packaged under the OPPS. Additional detailed suggestions for the Packaging Subcommittee should be submitted by e-mail to *APCPanel@cms.hhs.gov* with Packaging Subcommittee in the subject line.

Recommendation 5

We are accepting the APC Panel's recommendation that CMS provide information to the APC Panel on the impact of the creation of the imaging composite APCs on services to beneficiaries. Our proposal with regard to the imaging composite APCs is discussed in detail in section II.A.2.e.(5) of this proposed rule.

Recommendation 6

The Packaging Subcommittee of the APC Panel was established to review packaging issues. We are accepting the APC Panel's recommendation that the Packaging Subcommittee remain active until the next APC Panel meeting. We note that the APC Panel Packaging Subcommittee is currently active and that we will share additional issues and new data concerning the packaged status of codes with the APC Panel Packaging Subcommittee as that information becomes available.

4. Proposed Calculation of OPPS Scaled Payment Weights

Using the proposed 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 2011 shown in Addenda A and B to this proposed rule. In years prior to CY 2007, we standardized all the relative payment weights to APC 0601 (Mid Level Clinic Visit) because mid-level clinic visits were among the most frequently performed services in the hospital outpatient setting. We assigned APC 0601 a relative payment weight of 1.00 and divided the median cost for each APC by the median cost for APC 0601 to derive the relative payment weight for each APC.

Beginning with the CY 2007 OPPS (71 FR 67990), we standardized all of the relative payment weights 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 2011, 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 2011 median cost for APC 0606, for CY 2011 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 2011 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 2010 scaled relative weights to the estimated aggregate weight using the proposed CY 2011 unscaled relative weights. For CY 2010, we multiply the CY 2010 scaled APC relative weight applicable to a service paid under the OPPS by the volume of that service from CY 2009 claims to calculate the total weight for each service.

We then add together the total weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2011, we perform the same process using the proposed CY 2011 unscaled weights rather than scaled weights. We then calculate the weight scaler by dividing the CY 2010 estimated aggregate weight by the proposed CY 2011 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 2011 to estimated total weight in CY 2010 using CY 2009 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 2011 unscaled relative payment weights were adjusted by multiplying them by a proposed weight scaler of 1.3650 to ensure budget neutrality of the proposed CY 2011 relative weights.

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 2011 OPPS.

The proposed scaled relative payment weights listed in Addenda A and B to this proposed rule 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. Under the authority in section 1833(t)(3)(C)(iv) of the Act, for CY 2010, 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. The proposed hospital market basket increase for FY 2011 published in the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24062) prior to changes required by the Affordable Care Act and the HCERA is 2.4 percent. New section 1833(t)(3)(F)(iii) and (G)(i) of the Act (as added by 3401(i) of the Affordable Care Act and as amended by 10319(g) of such Act and section 1105(e) of HCERA) require a .25 percentage point reduction to the CY 2011 OPD fee schedule increase factor, resulting in a proposed CY 2011 OPPS market basket update of 2.15 percent. To set the proposed OPPS conversion factor for CY 2011, we increased the CY 2010 conversion factor of $67.241 by 2.15 percent. We announced the CY 2010 OPPS conversion factor of $67.241 in the Federal Register Notice CMS 1504-N, entitled "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System

and Ambulatory Surgical Center Payment System for CY 2010, and Extension of Part B Payment for Services Furnished by Hospitals or Clinics Operated by the Indian Health Service, Indian Tribes, or Tribal Organizations Made by the Affordable Care Act and ASC Changes Made By Previous Correction Notices," which is being published around the time of this proposed rule. Hospitals that fail to meet the reporting requirements of the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) are subject to a reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor. For a complete discussion of the HOP QDRP requirements and the payment reduction for hospitals that fail to meet those requirements, we refer readers to section XVI. of this proposed rule.

In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the proposed conversion factor for CY 2011 to ensure that any revisions we are proposing to make to our 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 1.0011 for wage index changes by comparing total payments from our simulation model using the FY 2011 IPPS proposed wage indices to those payments using the current (FY 2010) IPPS wage indices, as adopted on a calendar year basis for the OPPS, as indicated in the **Federal Register** notice announcing Affordable Care Act changes to the wage indices (See CMS 1504-N referenced above). For CY 2011, we are not proposing a change to our rural adjustment policy. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000. In addition, to accommodate the proposed cancer hospital adjustment described in section II.F. of this preamble, we calculated an additional

proposed budget neutrality factor of 0.9934 by comparing total payments from our simulation model for CY 2011 including the proposed adjustment for cancer hospitals to total payments from our simulation model for CY 2011 without the proposed adjustment for cancer hospitals.

For this proposed rule, we estimated that pass-through spending for both drugs and biologicals and devices for CY 2011 would equal approximately $86.9 million, which represents 0.20 percent of total projected CY 2011 OPPS spending. Therefore, the conversion factor would also be adjusted by the difference between the 0.14 percent estimate of pass-through spending for CY 2010 and the 0.20 percent estimate of CY 2011 pass-through spending. Finally, estimated payments for outliers remain at 1.0 percent of total OPPS payments for CY 2011.

The proposed OPD fee schedule increase factor of 2.15 percent for CY 2011, the required proposed wage index budget neutrality adjustment of approximately 1.0011, the proposed cancer hospital budget neutrality adjustment of 0.9934, and the proposed adjustment of 0.06 percent of projected OPPS spending for the difference in the pass-through spending resulted in a proposed conversion factor for CY 2011 of $68.267, which reflects the full proposed OPD fee schedule increase. To calculate the proposed CY 2011 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the HOP QDRP for the full CY 2011 payment update, we made all other adjustments discussed above, but used a proposed reduced market basket increase update factor of 0.15 percent (that is, an unadjusted OPD fee schedule increase factor of 2.4 percent reduced by 0.25 percentage point as required by the Affordable Care Act and

HCERA and 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 OPD quality reporting requirements) . This resulted in a proposed reduced conversion factor for CY 2011 of $66.930 for those hospitals that fail to meet the HOP QDRP requirements.

OPD Fee Schedule Increase Factor

In accordance with section 1833(t)(3)(C)(iv) of the Act, each year we update the OPPS conversion factor by an OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to 1833(t)(17) and 1833(t)(F), the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. For hospitals that do not meet the HOP QDRP reporting requirements discussed in section XVI of this proposed rule, the update is equal to the OPD fee schedule increase factor less an additional 2.0 percentage points. In accordance with these statutory provisions, in the CY 2010 OPPS final rule (74 FR 60419), we finalized an OPD fee schedule increase factor equal to the IPPS full market basket update of 2.1 percent. Hospitals that failed to meet the HOP QDRP reporting requirements were subject to a reduced OPD fee schedule increase factor of 0.1 percent.

We note that section 1833(t)(3)(F)(ii) and (G)(i) of the Act as added by section 3401(i) of Pub. L. 111-148 (Affordable Care Act) and as amended by section 10319(g) of such Act and section 1105(e) of Pub. L. 111-152 (HCERA) require that after determining the OPD fee schedule increase factor, the Secretary shall reduce such factor for CY 2010

by 0.25 percentage point. Therefore, the reduction of 0.25 percentage point applied to the full IPPS hospital operating market basket increase factor of 2.1 percent results in a revised OPD fee schedule increase factor of 1.85 percent. For hospitals that do not meet the HOP QDRP reporting requirements, the update is equal to the OPD fee schedule increase factor, less the additional 0.25 percentage point required by section 1833(t)(F)(ii) and (G)(i) of the Act, minus 2.0 percentage points. New section 1833(t)(3)(F) of the Act further states the application of 1833(t)(3)(F) may result in the OPD fee schedule increase factor under 1833(t)(3)(C)(iv) of the Act being less than zero for a year. Thus, the CY 2010 OPD fee schedule increase factor was 1.85 percent (that is, 2.1 percent minus 0.25 percentage point) for hospitals that met the HOP QDRP reporting requirements and negative 0.15 percent (2.1 percent, less the 0.25 percentage point, minus the 2.0 percentage points) for hospitals failing to meet the HOP QDRP reporting requirements.

As with the CY 2010 OPD fee schedule increase factor, new section 1833(t)(3)(F)(ii) and (G)(i) of the Act requires that the CY 2011 OPD fee schedule increase factor be reduced by 0.25 percentage point, subject to the hospital submitting quality information under rules established by the Secretary in accordance with section 1833(t)(17) of the Act. For hospitals that do not meet the HOP QDRP reporting requirements, the update is equal to the OPD fee schedule increase factor minus 0.25 percentage point minus 2.0 percentage points. Section 1833(t)(3)(F) of the Act further states that this amendment may result in the applicable percentage increase being less than zero.

In the FY 2011 IPPS proposed rule, consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2010 forecast, with historical data through the 2009 fourth quarter, we estimated that the FY 2011 IPPS market basket update would be 2.4 percent (75 FR 24016). However, consistent with the amendments to section 1833(t)(3)(F)(ii) and (G)(i) of the Act, we are required to reduce the OPD fee schedule increase factor by 0.25 percentage point. Therefore, the proposed market basket update to the CY 2011 OPD fee schedule increase factor is 2.15 percent (that is, the CY 2011 estimate of the OPD fee schedule increase factor of 2.4 percent minus 0.25 percentage point). For hospitals that do not meet the HOP QDRP reporting requirements, the proposed update to the OPPS conversion factor is 0.15 percent (that is, the adjusted CY 2011 estimate of the market basket rate-of increase of 2.15 percent minus 2.0 percentage points).

We are proposing to revise 42 CFR 419.32 to reflect the Affordable Care Act and HCERA requirements for 0.25 percentage point reductions to the OPPS fee schedule increase factor for CY 2010 and CY 2011 respectively in revised paragraph 42 CFR 419.32(b)(1)(iv).

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 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 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 still 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 2011 OPPS. We refer readers to section II.H. of this proposed rule for a description and example of how the wage index for a particular hospital is used to determine the payment for the hospital.

As discussed in section II.A.2.c. of this proposed rule, for estimating national median APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2011 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 IPPS wage index as the 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 and continue to believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and

logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually. Therefore, in accordance with our established policy, we are proposing to use the final FY 2011 version of the IPPS wage index used to pay IPPS hospitals to adjust the CY 2011 OPPS payment rates and copayment amounts for geographic differences in labor cost for all providers that participate in the OPPS, including providers that are not paid under the IPPS (referred to in this section as "non-IPPS" providers).

The Affordable Care Act contains a number of provisions affecting the FY 2011 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. These specific provisions are discussed in more detail in the supplemental FY 2011 IPPS/LTCH PPS proposed rule published June 2, 2010 in the Federal Register (75 FR 30920). The Affordable Care Act also required 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). We discuss this provision and how it applies to hospital outpatient departments in more detail below.

Section 10324 of the Affordable Care Act 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 2011 OPPS, we are proposing to adjust the wage index for all HOPDs, including those providers that are not paid under the IPPS, which are identified as being located in a frontier State, in the manner specified in the Affordable Care Act. Specifically, we would adjust the FY 2011 wage index, as adopted on a calendar year basis for the OPPS, for all hospitals paid under the OPPS, including non-IPPS hospitals, located in a frontier State to 1.00 in instances where the assigned FY 2011 wage index (that reflects MGCRB reclassifications, application of the rural floor and 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, then the wage index adjustment applicable for the hospital would also apply for the affiliated HOPD. We refer readers to the FY 2011 supplemental proposed rule published subsequent to the FY 2011 IPPS/LTCH proposed rule for detailed discussion regarding this provision, including our proposed 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, we are proposing to revise §419.43(c) of the regulations to incorporate the amendments made by section 10324 of the Affordable Care Act. Specifically, we would include a provision under a new paragraph (c)(2) to state that for services furnished beginning January 1, 2011, the wage adjustment factor referenced in

the existing regulations applicable to any HOPD that is located in a frontier State, as defined in the statute and regulations, may not be less than 1.00. We also are proposing to add a new paragraph (c)(3) to §419.43 to not consider these additional payments in budget neutrality.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2011 IPPS wage indices continue to reflect a number of adjustments implemented over the past few years, including revised Office of Management and Budget (OMB) standards for defining geographic statistical areas (Core-Based Statistical Areas or CBSAs), reclassification of hospitals to different geographic areas, rural floor provisions, an adjustment for out-migration labor patterns, an adjustment for occupational mix, and a policy for allocating hourly wage data among campuses of multicampus hospital systems that cross CBSAs. We refer readers to the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 23936 through 23956) and the supplemental proposed rule (75 FR 30918) for a detailed discussion of all proposed changes, including changes required by the Affordable Care Act, to the FY 2011 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.

The IPPS wage index that we are proposing to adopt in this proposed rule includes all reclassifications that are approved by the Medicare Geographic Classification Review Board (MGCRB) for FY 2011. We note that reclassifications under section 508 of Pub. L. 108-173 and certain special exception wage indices that were extended by

section 106(a) of Pub. L. 109- 432 (MIEA- TRHCA) and section 117 (a)(1) of Pub. L. 110-173 (MMSEA) were set to terminate September 30, 2008, but were further extended by section 124 of Pub. L. 110- 275 (MIPPA) through September 30, 2009 and, most recently, by section 3137 as amended by section 10317 of Pub. L. 111- 148 (Affordable Care Act) through September 30, 2010. We did not make any proposals related to these provisions for the CY 2010 OPPS wage index because Pub. L. 111-148 (Affordable Care Act) was enacted after issuance of the CY 2010 OPPS/ASC proposed and final rules. In accordance with section 10317 of Pub. L. 111-148, for CY 2010, we adopted all section 508 geographic reclassifications through September 30, 2010. Similar to our treatment of section 508 reclassifications extended under Pub. L. 110-173 (MMSEA) as described in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68586), hospitals with section 508 reclassifications will revert to their home area wage index, with out-migration adjustment if applicable, or a current MGCRB reclassification, from October 1, 2010 to December 31, 2010. In addition, as we did for CY 2009, we will recognize the revised wage index values for certain special exception hospitals from January 1, 2010 through December 31, 2010, 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. We refer readers to the FY 2010 section 508 reclassification **Federal Register** notice published on June 2, 2010 (75 FR 31118) for a detailed discussion of the changes to the wage indices as required by section 10317 of the Affordable Care Act. We also discuss the impact of the extension of reclassifications under section 508 and special exception wage indices in the **Federal Register** notice CMS-1504-N, entitled

"Medicare Program; Changes to the Hospital Outpatient Prospective Payment System for CY 2010, Changes to the Ambulatory Surgical Center Payment System for CY 2010, and Extension of Payment under Part B for Services Furnished by Hospitals or Clinics Operated by the Indian Health Service or Tribal Organizations Made by the Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 and Changes to the Ambulatory Surgical Center Payment System for CY 2010 Made By Previous Correction Notices" that will be published around the same time as this proposed rule. Because the provisions of section 10317 of the Affordable Care Act expired in 2010 and are not applicable to FY 2011, we are not making any proposals related to those provisions for the OPPS wage indices for CY 2011. However, we note that Congress is currently considering legislation that may further extend section 508 reclassifications and wage indexes for special exception providers for FY 2011, which would be applicable for the CY 2011 OPPS. We will implement any extension occurring before or during the comment period for this proposed rule in our final rule.

For purposes of the OPPS, we are proposing to continue our policy in CY 2011 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. We note that because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage adjustment. Table 4J in the **Federal Register** for the supplemental FY 2011 IPPS proposed rule (75 FR 31049), identifies counties eligible for the out-migration adjustment and providers receiving the 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 2011 OPPS.

As stated earlier in this section, we continue to believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. Therefore, we are proposing to use the final FY 2011 IPPS wage indices for calculating OPPS payments in CY 2011. With the exception of the out-migration wage adjustment table (Addendum L to this proposed rule), which includes non-IPPS hospitals paid under the OPPS, we are not reprinting the FY 2011 IPPS proposed 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 FY 2011 IPPS proposed 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 whose most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100-04), Chapter 4, Section 10.11). We are proposing to update the default ratios for CY 2011 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 2011, 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 CY 2011 proposed OPPS relative weights. Table 9 below lists the proposed CY 2011 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 adjusted ratios from submitted cost reports to reflect final settled status by applying the differential between settled to submitted overall CCR for the cost centers relevant to outpatient services from the most recent pair of final settled and submitted cost reports. We then weighted 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 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 2008 and 12 percent were for cost reporting periods ending in CY 2007. 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. In general, observed changes in the statewide average default CCRs between CY 2010 and CY 2011 are modest and the few significant changes are associated with areas that have a small number of hospitals.

TABLE 9.–-PROPOSED CY 2011 STATEWIDE AVERAGE CCRs

State	Urban/Rural	Proposed CY 2011 Default CCR	Previous Default CCR (CY 2010 OPPS Final Rule)
ALASKA	RURAL	0.479	0.499
ALASKA	URBAN	0.336	0.328
ALABAMA	RURAL	0.217	0.220
ALABAMA	URBAN	0.193	0.193
ARKANSAS	RURAL	0.248	0.251
ARKANSAS	URBAN	0.251	0.263
ARIZONA	RURAL	0.256	0.251
ARIZONA	URBAN	0.212	0.217
CALIFORNIA	RURAL	0.198	0.208
CALIFORNIA	URBAN	0.209	0.210
COLORADO	RURAL	0.347	0.345
COLORADO	URBAN	0.248	0.255
CONNECTICUT	RURAL	0.372	0.375
CONNECTICUT	URBAN	0.317	0.319
DISTRICT OF COLUMBIA	URBAN	0.319	0.324
DELAWARE	RURAL	0.279	0.320
DELAWARE	URBAN	0.362	0.363
FLORIDA	RURAL	0.193	0.198
FLORIDA	URBAN	0.181	0.184
GEORGIA	RURAL	0.262	0.265
GEORGIA	URBAN	0.235	0.246
HAWAII	RURAL	0.359	0.359
HAWAII	URBAN	0.308	0.307
IOWA	RURAL	0.266	0.332
IOWA	URBAN	0.293	0.302
IDAHO	RURAL	0.507	0.507
IDAHO	URBAN	0.417	0.409
ILLINOIS	RURAL	0.256	0.273

State	Urban/Rural	Proposed CY 2011 Default CCR	Previous Default CCR (CY 2010 OPPS Final Rule)
ILLINOIS	URBAN	0.245	0.253
INDIANA	RURAL	0.307	0.299
INDIANA	URBAN	0.278	0.296
KANSAS	RURAL	0.285	0.291
KANSAS	URBAN	0.225	0.226
KENTUCKY	RURAL	0.224	0.223
KENTUCKY	URBAN	0.249	0.254
LOUISIANA	RURAL	0.265	0.271
LOUISIANA	URBAN	0.244	0.259
MARYLAND	RURAL	0.290	0.294
MARYLAND	URBAN	0.262	0.267
MASSACHUSETTS	URBAN	0.323	0.323
MAINE	RURAL	0.457	0.433
MAINE	URBAN	0.452	0.452
MICHIGAN	RURAL	0.313	0.318
MICHIGAN	URBAN	0.322	0.320
MINNESOTA	RURAL	0.498	0.502
MINNESOTA	URBAN	0.327	0.330
MISSOURI	RURAL	0.261	0.266
MISSOURI	URBAN	0.262	0.270
MISSISSIPPI	RURAL	0.241	0.244
MISSISSIPPI	URBAN	0.191	0.192
MONTANA	RURAL	0.428	0.438
MONTANA	URBAN	0.422	0.462
NORTH CAROLINA	RURAL	0.269	0.270
NORTH CAROLINA	URBAN	0.282	0.285
NORTH DAKOTA	RURAL	0.357	0.333
NORTH DAKOTA	URBAN	0.390	0.361
NEBRASKA	RURAL	0.335	0.340
NEBRASKA	URBAN	0.263	0.260
NEW HAMPSHIRE	RURAL	0.340	0.329
NEW HAMPSHIRE	URBAN	0.291	0.285
NEW JERSEY	URBAN	0.236	0.235
NEW MEXICO	RURAL	0.272	0.259
NEW MEXICO	URBAN	0.316	0.329

State	Urban/Rural	Proposed CY 2011 Default CCR	Previous Default CCR (CY 2010 OPPS Final Rule)
NEVADA	RURAL	0.280	0.296
NEVADA	URBAN	0.180	0.187
NEW YORK	RURAL	0.414	0.423
NEW YORK	URBAN	0.378	0.383
OHIO	RURAL	0.341	0.350
OHIO	URBAN	0.248	0.250
OKLAHOMA	RURAL	0.265	0.267
OKLAHOMA	URBAN	0.217	0.225
OREGON	RURAL	0.301	0.303
OREGON	URBAN	0.353	0.344
PENNSYLVANIA	RURAL	0.276	0.280
PENNSYLVANIA	URBAN	0.210	0.223
PUERTO RICO	URBAN	0.520	0.514
RHODE ISLAND	URBAN	0.299	0.299
SOUTH CAROLINA	RURAL	0.235	0.232
SOUTH CAROLINA	URBAN	0.235	0.242
SOUTH DAKOTA	RURAL	0.314	0.320
SOUTH DAKOTA	URBAN	0.256	0.261
TENNESSEE	RURAL	0.229	0.233
TENNESSEE	URBAN	0.211	0.214
TEXAS	RURAL	0.249	0.251
TEXAS	URBAN	0.218	0.222
UTAH	RURAL	0.397	0.397
UTAH	URBAN	0.385	0.400
VIRGINIA	RURAL	0.244	0.242
VIRGINIA	URBAN	0.257	0.255
VERMONT	RURAL	0.415	0.413
VERMONT	URBAN	0.397	0.397
WASHINGTON	RURAL	0.370	0.365
WASHINGTON	URBAN	0.335	0.340
WISCONSIN	RURAL	0.387	0.384
WISCONSIN	URBAN	0.337	0.329
WEST VIRGINIA	RURAL	0.292	0.283
WEST VIRGINIA	URBAN	0.336	0.339
WYOMING	RURAL	0.396	0.407

State	Urban/Rural	Proposed CY 2011 Default CCR	Previous Default CCR (CY 2010 OPPS Final Rule)
WYOMING	URBAN	0.300	0.315

E. Proposed OPPS Payment 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 payment (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 ended 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 (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, section 3121(a) of the Affordable Care Act, Pub. L. 111-148, amended section 1833(t)(7)(D)(i)(III) of the Act by extending the period of TOPs to rural hospitals that are not SCHs with 100 beds or fewer for 1 year, for services provided before January 1, 2011. Section 3121(a) of Public Law 111-148, 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 Pub. L. 111-148 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 Public Law 111-148, 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, we are proposing to update section 419.70(d) of the regulations to reflect the TOPs extensions and amendments described in section 3121 of Pub. L. 111-148.

Effective for services provided on or after January 1, 2011, rural hospitals having 100 or fewer beds that are not SCHs and SCHs (including EACHs) will no longer be eligible for hold harmless TOPs, in accordance with section 3121 of Public Law 111-148.

2. Proposed Adjustment for Rural SCHs Implemented in CY 2006 Related to Pub. L. 108-173 (MMA)

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, fewer than 10 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 CY 2008 and CY 2009. 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 2011 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. 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 Cancer Hospitals Described in Section 1886(d)(1)(B)(v) of the Act

1. Background

Since the inception of the hospital outpatient prospective payment system (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 inpatient prospective payment system (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 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 such services for the portions of the hospital's cost reporting period (or periods) occurring in the year and the base payment to cost ratio (base 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) 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)(1)(v)(B) 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) 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 states that if the cancer hospitals' costs are determined to be greater than the costs of other hospitals paid under the OPPS, the Secretary shall provide an appropriate adjustment to reflect these higher costs. Section 3138 of the Affordable Care Act also requires that this adjustment be budget neutral, and it would be effective for outpatient services provided at cancer hospitals on or after January 1, 2011. Cancer hospitals described in section 1886(d)(1)(B)(v) of the Act remain eligible for TOPs payment (which are not budget neutral) and outlier payments (which are budget neutral).

1. 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 sole community hospitals (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 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. With such a small sample size (11 out of approximately 4,000 hospitals paid under the OPPS), we are 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 identify costliness and determine a cancer hospital adjustment.

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 including average cost per unit for a hospital and the hospitals average APC relative weight as an indicator of the hospitals resource intensity, as measured by the APC relative weights. We used these variables to calculate univariate statistics that describe the costliness 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 believe that we can assume 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 as we did for the rural 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 (discussed in detail in section II.A. of this proposed rule).

This analytical dataset includes 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 CY 2011 OPPS. We create this dataset from the hospital specific service utilization files that we use to model budget neutrality and to perform impact analyses after we complete estimating a median cost (or equivalent amount depending on unique APC methodologies as discussed in section II of this proposed rule) for each APC. Using the CY 2009 claims that we use to model the CY 2011 proposed OPPS, we use the utilization on those claims to model APC payment under the CY 2011 proposed payment policies, such as proposed payment for drugs and biologicals at ASP+6 percent and proposed reassignment of some HCPCS codes to different APCs. We then summarized this 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. The calculation of these summary files are discussed in Stage 6 of our claims accounting narrative available under supporting documentation for this proposed rule on the CMS Web site at: http://www.cms.gov/HospitalOutpatientPPS/HORD/. After summarizing modeled payment to the hospital-level, we removed 48 hospitals in Puerto Rico from our dataset,

because we do not believe that their cost structure reflects the costs of most hospitals paid under the OPPS and 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 the 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 this 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 use these variables because they are key indicators of costliness under the modeled OPPS system, and they allow us to assess the relative costliness of classes of hospitals under the proposed CY 2011 OPPS. We further discuss these variables in our CY 2006 proposed rule analysis (70 FR 42698 through 42701). 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 are proposing 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 this data to calculate the descriptive univariate statistics for cancer hospitals appearing in Table 10 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 observe 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 remains 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 lead us to conclude that cancer hospitals are more costly than other hospitals paid under the OPPS, even without the inferential statistical models that we typically employ.

Table 10. - Means and Standard Deviations for Key Variables by Cancer and Non-Cancer OPPS Hospitals

	Cancer Hospitals		Non-Cancer Hospitals	
Variable	**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

2. Proposed Adjustment for Certain Cancer Hospitals

Having reviewed the cost data from the standard analytic database and determined that cancer hospitals are more costly than other hospitals within 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. Analyses on our standard analytic database and descriptive statistics presented in Table 10 above, did not consider TOPs in assessing costliness of cancer hospitals relative to other hospitals furnishing services under section 1833(t) of the Act. This is because section 3138 of the Affordable Care Act requires that any cancer adjustment be made within the budget neutral system. In making a determination about a payment adjustment subject to budget neutrality, we believe it is appropriate to assess costliness and payments within the budget neutral payment system. We note that TOPs are based on reasonable cost and are

not part of the budget neutral payment system. Further, 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 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 relative weight under the proposed modeled CY 2011 OPPS. The cost report data we selected for the analysis was limited to the OPPS-specific payment and cost data available on Worksheet E Part B, which is also where TOPs are calculated including 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 this cost report data cannot provide an estimate of cost per unit after controlling for other potential factors that could influence cost per unit, we can use 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 also indicate that costs relative to payments at cancer hospitals are 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), as discussed in section II.A. of this proposed rule, that we used to calculate the CCRs that

we used to estimate median costs for this proposed CY 2011 OPPS. Using this cost report data, we included data from Worksheet E Part B for each hospital, keeping 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 2009 claims data that we used to model the CY 2011 proposed APC relative weights (3933 hospitals) because we used the claims from these hospitals to calculate the estimated costs we used for the descriptive statistics in our first analysis and because it is appropriate to use the same set of hospitals that we are using to calibrate the modeled proposed CY 2011 OPPS. The cancer hospitals in this data set largely had cost report data from cost reporting periods ending in FY 2008 and FY 2009. The cost report data for the other hospitals were from cost report periods with fiscal year ends ranging from 2005 to 2009. We then removed the cost report data for 48 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 may bias the results of the study. We also removed 301 hospitals with cost report data that was 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 3584 hospitals with cost report data. We believe that the costs, PPS payments, and TOPs reported on Worksheet E part B for the hospitals included in our CY 2011 modeling should be sufficiently accurate for assessing hospital's relative costliness because all of the key elements that we believe to be necessary for the analysis (payment, cost and TOPs) are contained on this worksheet.

Using this much smaller dataset of cost report data, we estimate that on average, the OPPS payments to the 11 cancer hospitals, not including TOPs, are approximately 62 percent of reasonable cost (that is, we calculate a PCR of 0.615 for the cancer hospitals), whereas, we estimate that, on average, the OPPS payments to other hospitals paid under the OPPS are approximately 87 percent of reasonable cost (resulting in a PCR of 0.868). Individual cancer hospitals' OPPS PCRs range from approximately 48 percent to approximately 82 percent. When TOPS are included in the calculation of the PCR, cancer hospitals, as a group, receive payments that are approximately 83 percent of reasonable cost, which is still lower than the average PCR of other OPPS hospitals of approximately 87 percent of reasonable cost. Considering this data, we find that the cancer hospitals are more costly than other hospitals paid under the OPPS. The dataset of hospital cost report data that we used to model this proposed adjustment is available under supporting documentation for this proposed rule on the CMS Web site at: http://www.cms.gov/HospitalOutpatientPPS/HORD/.)

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 paid under the OPPS and our findings above 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 are proposing an adjustment for cancer hospitals to reflect these higher costs effective January 1, 2011, as mandated by section 3138 of the Affordable Care Act. 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. Therefore, we propose 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 all other hospitals paid under 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 their individual PCR (without TOPs) and the weighted average PCR of the other hospitals paid under OPPS.

This proposed methodology would result in the proposed percentage payment adjustments for the 11 cancer hospitals appearing in Table 11. We propose that this hospital-specific adjustment would be applied to the wage adjusted payments for all items, except for items and services paid at charges adjusted to cost or devices receiving pass-through status defined in 42 CFR 419.66. The proposed cancer hospital adjustment would not be applied to items and services paid at charges adjusted to cost because these items and services are always paid the estimated full cost of the item or service. We are proposing to amend 42 CFR to add new section 419.43(i)(2) which would establish the amount of the adjustment to cancer hospitals. We also propose that this adjustment would be budget neutral as set forth in proposed new section 42 CFR 419.43(i)(3),

consistent with section 3138 of the Affordable Care Act. We note that outlier payments would be appropriately assessed after application of the cancer adjustment and that TOPs would continue to apply. 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 payments for cancer hospitals. 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. As a means of buffering the financial risk associated with a prospective payment system, both adjustments (outliers and TOPs) only should be assessed after final payments have been made. Because outlier payments are made within the budget neutrality, outlier payments should be assessed after all budget neutral payments for an individual service have been made, including the cancer adjustment. The TOPs payments would be assessed after all payments have been made for a cost reporting period. We note that the proposed adjustment for all cancer hospitals would result in an estimated aggregate increase in OPPS payments to cancer hospitals of 41.2 percent for CY 2011, based on cost report data.

TABLE 11. – PROPOSED HOSPITAL-SPECIFIC ADJUSTMENT FOR CANCER HOSPITALS WITHOUT REGARD TO TOPs AND OUTLIER PAYMENTS

Provider Number	Hospital	Percent of Increase Without TOPs or Outlier Payment
050146	CITY OF HOPE HELFORD CLIN RESEARCH HOSP	5.9%
050660	USC KENNETH NORRIS JR CANCER HOSPITAL	11.5%

Provider Number	Hospital	Percent of Increase Without TOPs or Outlier Payment
390196	HOSP OF THE FOX CHASE CANCER CENTER	13.6%
360242	JAMES CANCER HOSPITAL & SOLOVE RESEARCH INSTITUTE	15.7%
330354	ROSWELL PARK CANCER INSTITUTE	16.3%
100079	UNIV OF MIAMI HOSP & CLINIC	21.5%
100271	H LEE MOFFITT CANCER CENTER & RESEARCH INSTITUTE	29.4%
330154	MEM HOSP FOR CANCER AND ALLIED DISEASES	36.4%
220162	DANA-FARBER CANCER INSTITUTE	42.2%
500138	SEATTLE CANCER CARE ALLIANCE	47.6%
450076	UNIV OF TEXAS M D ANDERSON CANCER CENTER	82.6%
Proposed Aggregate Adjustment		41.2%

We propose to recalibrate the "other hospital" PCR target amount and the hospital-specific percentage adjustment for each cancer hospital periodically, but not every year, because we do not believe that these amounts will change so drastically in any given year to warrant annual recalculation. In the event that a cancer hospital has a PCR that is higher than the volume weighted average PCR for all hospitals, we propose that the specific hospital would not be eligible for this adjustment. We believe that this would indicate that the hospital's costs do not exceed the costs incurred by other hospitals furnishing services under the OPPS and, therefore, an adjustment would not be required and would be unnecessary. We note that the TOPS provision remains in effect and that we will continue to make TOPS to cancer hospitals that continue to have all final OPPS

payments (including but not limited to outlier payments, the wage adjustment, and this new cancer hospital adjustment), that are lower than their pre-BBA payment amount. If this proposed adjustment is finalized, we estimate that only one cancer hospital would continue to receive TOPS. We propose to update the hospital-specific cancer hospital payment adjustments in Table 11 using the more recent cost reports that become available for the CY 2011 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 2010, 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 $2,175 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 2009 OPPS payment, using available CY 2009 claims and the revised OPPS expenditure estimate for the President's Budget for FY 2011, is approximately 1.0 percent of the total aggregated OPPS payments. Therefore, for CY 2009, we estimate that we paid at the CY 2009 outlier target of 1.0 percent of total aggregated OPPS payments.

As explained in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60426 through 60427), we set our projected target for aggregate outlier payments at 1.0 percent of the aggregate total payments under the OPPS for CY 2010. The outlier thresholds were set so that estimated CY 2010 aggregate outlier payments would equal 1.0 percent of the total aggregated payments under the OPPS. Using CY 2009 claims data and CY 2010 payment rates, we currently estimate that the aggregate outlier payments for CY 2010 would be approximately 0.85 percent of the total CY 2010 OPPS payments. The difference between 1.0 percent and 0.85 percent is reflected in the regulatory impact analysis in section XXIII. of this proposed rule. We note that we provide estimated CY 2011 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

For CY 2011, we are proposing to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS for outlier payments. We are proposing that a portion of that 1.0 percent, specifically 0.04 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 X.D. of this proposed rule, for CMHCs, we are proposing to continue a policy, that if a CMHC's cost for partial hospitalization services, paid under either APC 0172 (Level I Partial Hospitalization (3 services)) or APC 0173 (Level II Partial Hospitalization (4 or more services)), 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 X.D. of this proposed rule.

To ensure that the estimated CY 2011 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 $2,025 fixed-dollar threshold. This proposed threshold reflects the methodology discussed below in this section, as well as the proposed APC recalibration for CY 2011.

We calculated the proposed fixed-dollar threshold for this proposed rule using largely the same methodology as we did in CY 2009 (73 FR 41462). For purposes of

estimating outlier payments for this proposed rule, we used the hospital-specific overall ancillary CCRs available in the April 2010 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 2009 claims to model the CY 2011 OPPS. In order to estimate the proposed CY 2011 hospital outlier payments for this proposed rule, we inflated the charges on the CY 2009 claims using the same inflation factor of 1.1059 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24068). We used an inflation factor of 1.0516 to estimate CY 2010 charges from the CY 2009 charges reported on CY 2009 claims. The methodology for determining this charge inflation factor was discussed in the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24068). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65845), we believe that the use of this charge inflation factor is 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 proposed to apply for the FY 2011 IPPS outlier calculation to the CCRs used to simulate

the proposed CY 2011 OPPS outlier payments that determine the fixed-dollar threshold. Specifically, for CY 2011, we are proposing to apply an adjustment of 0.9890 to the CCRs that were in the April 2010 OPSF to trend them forward from CY 2010 to CY 2011. The methodology for calculating this adjustment is discussed in the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24068 through 24070).

Therefore, to model hospital outlier payments for this proposed rule, we applied the overall CCRs from the April 2010 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9890 to approximate CY 2011 CCRs) to charges on CY 2009 claims that were adjusted (using the proposed charge inflation factor of 1.1059 to approximate CY 2011 charges). We simulated aggregated CY 2011 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple threshold constant and assuming that outlier payment would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2011 OPPS payments. We estimated that a proposed fixed-dollar threshold of $2,025, 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 $2,025 threshold are met. For CMHCs, if a CMHC's cost for partial hospitalization services, paid under either APC 0172 or APC

0173, exceeds 3.40 times the payment 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 HOP QDRP requirements. For hospitals that fail to meet the HOP QDRP requirements, we are proposing to continue our policy that we implemented in CY 2009 that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the HOP QDRP, we refer readers to section XVI. of this proposed rule.

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 ensures accurate outlier payments for those facilities whose CCRs fluctuate significantly relative to the CCRs of other facilities, and who receive a significant amount of outlier payments. As under the IPPS, we do not

adjust the fixed-dollar threshold or amount of total OPPS payment set aside for outlier payments for reconciliation activity because such action would be contrary to the prospective nature of the system. Our outlier threshold calculation assumes that overall ancillary CCRs accurately estimate hospital costs based on the information available to us at the time we set the prospective fixed-dollar outlier threshold. For these reasons, we are not incorporating any assumptions about the effects of reconciliation into our calculation of the proposed 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. The payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this proposed rule and the relative weight determined under section II.A. of this proposed rule. Therefore, the proposed national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule was calculated by multiplying the proposed CY 2011 scaled weight for the APC by the proposed CY 2011 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 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 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 Data Reporting Program (HOP QDRP) requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the HOP QDRP, we refer readers to section XVII.D. of this proposed rule.

We demonstrate in the steps below how to determine the APC payments that would be made in a calendar year under the OPPS to a hospital that fulfills the HOP QDRP requirements and to a hospital that fails to meet the HOP QDRP 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 HOP QDRP requirements because the national unadjusted payment rates for these services are updated by the OPD fee schedule increase factor.

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 should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the HOP QDRP 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 HOP QDRP 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 HOP QDRP requirements in order to receive the full CY 2011 OPPS increase factor.

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 still 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 2011 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 section 3137 of the Affordable Care Act, expires on September 30, 2010, and, therefore, are not applicable under the IPPS for FY 2011. Therefore, these reclassifications will not apply to the CY 2011 OPPS. (For further discussion of the changes to the FY 2011 IPPS wage indices, as applied to the CY 2011 OPPS, we refer readers to section II.C. of this proposed rule.) In section II.C. of this proposed rule, we also discuss our proposal to implement section 10324 of the Affordable Care Act, which establishes a wage index floor of 1.00 for frontier States, effective for services furnished on and after January 1, 2011.

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 contains the qualifying counties and the associated proposed wage index increase developed for the FY 2011 IPPS and published as Table 4J in the FY 2011 IPPS/LTCH PPS proposed rule (75 FR 24182). 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 proposed 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 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 HOP QDRP 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 2011 full national unadjusted payment rate for APC 0019 is $335.76. The proposed reduced national unadjusted payment rate for a hospital that fails to meet the HOP QDRP requirements is $329.04. 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 2011 wage index for a provider located in CBSA 35644 in New York is 1.3154. The proposed labor-related portion of the full national unadjusted payment is $264.99 (.60 * $335.76 *1.3154). The proposed labor-related portion of the

reduced national unadjusted payment is $259.69 (.60 * $329.04 *1.3154). The proposed nonlabor-related portion of the full national unadjusted payment is $134.30 (.40 * $335.76). The proposed nonlabor-related portion of the reduced national unadjusted payment is $131.62 (.40 * $329.04). The sum of the labor-related and nonlabor-related portions of the full national adjusted payment is $399.29 ($264.99 + $134.30). The sum of the reduced national adjusted payment is $391.31 ($259.69 + $131.62).

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. Until CY 2011, sections 1834(d)(2)(C)(ii) and 1834(d)(3)(C)(ii) of the Act further require that the copayment for screening flexible sigmoidoscopies and screening colonoscopies be equal to 25 percent of

the payment amount. Since the beginning of the OPPS, we have applied the 25 percent copayment to screening flexible sigmoidoscopies and screening colonoscopies. However, section 4104 of the Affordable Care Act eliminated the coinsurance (to which section 1833(t)(2)(B) refers as the "copayment") for preventive services 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. We discuss our proposal to implement this provision in section XII.B. of this proposed rule.

2. Proposed OPPS Copayment Policy

For CY 2011, 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 national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2011, are shown in Addenda A and B to this proposed rule. As discussed in section XVI.D. of this proposed rule, for CY 2011, the 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 HOP QDRP 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, $67.16 is 20 percent of the full national unadjusted payment rate of $335.76. For APCs with only a minimum unadjusted copayment in Addendum A and B of this proposed rule, 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 HOP QDRP 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, 2011, are shown in Addenda A and B to this proposed rule. We note that the national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the full market basket conversion factor increase, as discussed in section XVI.D. of this proposed rule.

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

A. Proposed OPPS Treatment of New HCPCS and CPT 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 Table12 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.

TABLE 12.—COMMENT TIMEFRAME FOR NEW OR REVISED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 2010	Level II HCPCS Codes	April 1, 2010	CY 2011 OPPS/ASC proposed rule	CY 2011 OPPS/ASC final rule with comment period
July 1, 2010	Level II HCPCS Codes	July 1, 2010	CY 2011 OPPS/ASC proposed rule	CY 2011 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and III	July 1, 2010	CY 2011 OPPS/ASC	CY 2011 OPPS/ASC final

	CPT codes		proposed rule	rule with comment period
October 1, 2010	Level II HCPCS Codes	October 1, 2010	CY 2011 OPPS/ASC final rule with comment period	CY 2012 OPPS/ASC final rule with comment period
January 1, 2011	Level II HCPCS Codes	January 1, 2011	CY 2011 OPPS/ASC final rule with comment period	CY 2012 OPPS/ASC final rule with comment period
	Category I and III CPT Codes	January 1, 2011	CY 2011 OPPS/ASC final rule with comment period	CY 2012 OPPS/ASC final rule with comment period

This process is discussed in detail below and we have separated our discussion into two sections based on whether we are proposing to solicit public comments in this CY 2011 OPPS/ASC proposed rule on a specific group of the CPT and Level II HCPCS codes or whether we are proposing to solicit public comments on another specific group of the codes in the CY 2011 OPPS/ASC final rule with comment period. We note that we sought public comments in the CY 2010 OPPS/ASC final rule with comment period on the new CPT and Level II HCPCS codes that were effective January 1, 2010. We also sought public comments in the CY 2010 OPPS/ASC final rule with comment period on the new Level II HCPCS codes effective October 1, 2009. These new codes with an effective date of October 1, 2009, or January 1, 2010, 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 2010 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 2010 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 2011 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 Proposed Rule

Effective April 1 and July 1 of CY 2010, we make effective a total of 22 new Level II HCPCS codes, 4 new Category I CPT vaccine codes, and 11 new Category III CPT codes that were not addressed in the CY 2010 OPPS/ASC final rule with comment period that updated the OPPS. Twenty-two new Level II HCPCS codes are effective for the April and July 2010 updates, and of the 22 new HCPCS codes, a total of 14 Level II HCPCS codes are newly recognized for separate payment under the OPPS.

Through the April 2010 OPPS quarterly update CR (Transmittal 1924, Change Request 6857, dated February 26, 2010), we allowed separate payment for a total of six of the 22 Level II HCPCS codes. Specifically, as displayed in Table 13 below, these included HCPCS code C9258 (Injection, telavancin, 10 mg), C9259 (Injection, pralatrexate, 1 mg), C9260 (Injection, ofatumumab, 10 mg), C9261 (Injection, ustekinumab, 1 mg), C9262 (Fludarabine phosphate, oral, 1 mg), and C9263 (Injection, ecallantide, 1 mg).

In addition to the six HCPCS C-codes, five new HCPCS G-codes were made effective on April 1, 2010. We did not recognize the five new HCPCS G-codes for separate payment under the OPPS because they were either paid under another Medicare payment system or were noncovered services under Medicare. Specifically, we assigned

HCPCS G0432 (Infectious agent antigen detection by enzyme immunoassay (EIA) technique, qualitative or semi-quantitative, multiple-step method, HIV-1 or HIV-2, screening), G0433 (Infectious agent antigen detection by enzyme-linked immunosorbent assay (ELISA) technique, antibody, HIV-1 or HIV-2, screening), G0435 (Infectious agent antigen detection by rapid antibody test of oral mucosa transudate, HIV-1 or HIV-2, screening), and G9143 (Warfarin responsiveness testing by genetic technique using any method, any number of specimen(s)), to status indicator "A" (Not paid under OPPS. Paid by fiscal intermediaries/MACs under a fee schedule or payment system other than OPPS) to indicate that these services are paid under the Medicare Clinical Laboratory Fee Schedule (CLFS). Further, we did not recognize for separate payment HCPCS G9147 (Outpatient Intravenous Insulin Treatment (OIVIT) and assigned it to status indicator "E" (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) because this service is nationally a noncovered service under Medicare.

TABLE 13.—LEVEL II HCPCS CODES WITH A CHANGE IN OPPS STATUS INDICATOR OR NEWLY IMPLEMENTED IN APRIL 2010

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 Status Indicator	Proposed CY 2011 APC
C9258	Injection, telavancin, 10 mg	G	9258
C9259	Injection, pralatrexate, 1 mg	G	9259
C9260	Injection, ofatumumab, 10 mg	G	9260
C9261	Injection, ustekinumab, 1 mg	G	9261
C9262*	Fludarabine phosphate, oral, 1 mg	G	9262
C9263	Injection, ecallantide, 1 mg	G	9263
G0432	Infectious agent antibody detection by enzyme immunoassay (EIA) technique, qualitative or semiquantitative, multiple-step method, HIV-1 or HIV-2, screening	A	NA
G0433	Infectious agent antibody detection by enzyme-linked	A	NA

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 Status Indicator	Proposed CY 2011 APC
	immunosorbent assay (ELISA) technique, antibody, HIV-1 or HIV-2, screening		
G0435	Infectious agent detection by rapid antibody test of oral mucosa transudate, HIV-1 or HIV-2, screening	A	NA
G9143	Warfarin responsiveness testing by genetic technique using any method, any number of specimen(s)	A	NA
G9147	Outpatient Intravenous Insulin Treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine urea nitrogen (UUN); and/or, arterial, venous or capillary glucose; and/or potassium concentration	E	NA

*Level II HCPCS code C9262 was deleted June 30, 2010, and replaced with HCPCS code Q2025 effective July 1, 2010.

Through the July 2010 OPPS quarterly update CR (Transmittal 1980, Change Request 6996, dated June 4, 2010), which included HCPCS codes that were made effective July 1, 2010, we allowed separate payment for 8 of the 22 new Level II HCPCS codes. Specifically, as displayed in Table 14, we provided separate payment for HCPCS codes C9264 (Injection, tocilizumab, 1 mg), C9265 (Injection, romidepsin, 1 mg), C9266 (Injection, collagenase clostridium histolyticum, 0.1 mg), C9267 (Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO), C9268 (Capsaicin, patch, 10cm2), C9367 (Skin substitute, Endoform Dermal Template, per square centimeter), Q2025 (Fludarabine phosphate oral, 10mg), and C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies).

We note that HCPCS code C9262 was made effective April 1, 2010, and deleted June 30, 2010, when it was replaced with HCPCS code Q2025. As discussed in section

V.A.3. of this proposed rule, pass-through status began for this drug on April 1, 2010. Because HCPCS code Q2025 describes the same drug as HCPCS code C9262, 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 14. Specifically, HCPCS code Q2025 is assigned to APC 9262 and status indicator "G."

Of the 12 HCPCS codes that were made effective July 1, 2010, we did not recognize for separate payment four HCPCS codes. Specifically, we did not recognize HCPCS codes G0428 (Collagen Meniscus Implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)), G0429 (Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (LDS) (e.g., as a result of highly active antiretroviral therapy), Q2026 (Injection, Radiesse, 0.1 ml), and Q2027 (Injection, Sculptra, 0.1 ml). Under the hospital OPPS, we have assigned HCPCS code G0428 to status indicator "E" (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) because this service is nationally noncovered by Medicare. Further, because HCPCS code C9800 describes both the injection procedure and the dermal filler supplies, we have assigned HCPCS codes G0429, Q2026, and Q2027 to status indicator "B" to indicate that these HCPCS codes are not recognized by OPPS when submitted on an outpatient hospital Part B bill type 12x and 13x. Specifically, hospitals must report HCPCS code C9800 to report the dermal filler supplies and the dermal filler injection procedure. Under the hospital OPPS, we have assigned HCPCS code C9800 to APC 0135 with a status indicator "T". We refer readers to Table 14 below for a complete list of the HCPCS codes that were made effective July 1, 2010.

TABLE 14.—NEW LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2010

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 Status Indicator	Proposed CY 2011 APC	Proposed CY 2011 Payment Rate
C9264	Injection, tocilizumab, 1 mg	G	9264	$3.52
C9265	Injection, romidepsin, 1 mg	G	9265	$223.78
C9266	Injection, collagenase clostridium histolyticum, 0.1 mg	G	9266	$382.78
C9267	Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO	G	9267	$122.07
C9268	Capsaicin, patch, 10cm2	G	9268	$11.18
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	G	9367	$4.35
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies	T	0135	$298.46
G0428	Collagen Meniscus Implant procedure for filling meniscal defects (e.g., CMI, collagen scaffold, Menaflex)	E	NA	NA
G0429	Dermal Filler injection(s) for the treatment of facial lipodystrophy syndrome (LDS) (e.g., as a result of highly active antiretroviral therapy)	B	NA	NA
Q2025*	Fludarabine phosphate oral, 10mg	G	9262	$8.18
Q2026	Injection, Radiesse, 0.1 ml	B	NA	NA
Q2027	Injection, Sculptra, 0.1 ml	B	NA	NA

*Level II HCPCS code Q2025 was previously described under HCPCS code C9262.

For CY 2011, 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 2010 OPPS quarterly

update CR, we allow separate payment for 10 of the 11 new Category III CPT codes effective July 1, 2010. Specifically, as displayed in Table 15 below, we allow separate payment for CPT codes 0223T (Acoustic cardiography, including automated analysis of combined acoustic and electrical intervals; single, with interpretation and report), 0224T (Multiple, including serial trended analysis and limited reprogramming of device parameter - AV or VV delays only, with interpretation and report), 0225T (Multiple, including serial trended analysis and limited reprogramming of device parameter - AV and VV delays, with interpretation and report), 0226T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed), 0227T (Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)), 0228T (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; single level), 0229T (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; each additional level (List separately in addition to code for primary procedure)), 0230T (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level), 0231T (Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; each additional level (List separately in addition to code for primary procedure)), and 0232T (Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed). We note that CMS has issued a noncoverage determination (NCD) specifically for chronic, non-healing cutaneous wounds and acute surgical wounds when the autologous platelet rich plasma (PRP) is applied directly to the closed incision or

for dehiscent wounds. Category III CPT code 0232T has been assigned to APC 0340 to provide a payment amount when payment is appropriate, both under the NCD provisions and any local coverage determinations. Under the hospital OPPS, Category III CPT code 0233T (Skin advanced glycation endproducts (AGE) measurement by multi-wavelength fluorescent spectroscopy) has been assigned to status indicator "A" and hospital payment for this test will be made under the MPFS.

Further, CMS does not recognize the four new H1N1 Category I CPT vaccine codes that are effective on July 1, 2010, for separate payment under the OPPS because we already recognize an existing HCPCS G-code for reporting the H1N1 vaccine, specifically HCPCS code G9142 (Influenza a (h1n1) vaccine, any route of administration), which is effective September 1, 2009. We have assigned HCPCS code G9142 to status indicator "E" under the OPPS because the vaccine is expected to be free. Consequently, Category I CPT vaccine codes 90664 (Influenza virus vaccine, pandemic formulation, live, for intranasal use), 90666 (Influenza virus vaccine, pandemic formulation, split virus, preservative free, for intramuscular use), 90667 (Influenza virus vaccine, pandemic formulation, split virus, adjuvanted, for intramuscular use), and 90668 (Influenza virus vaccine, pandemic formulation, split virus, for intramuscular use), are assigned to status indicator "E" (Not paid under OPPS or any other Medicare payment system). These codes and their status indicators are listed in Table 15 below.

TABLE 15.—CATEGORY I VACCINE AND CATEGORY III CPT CODES IMPLEMENTED IN JULY 2010

CY 2010 CPT Code	CY 2010 Long Descriptor	Proposed CY 2011 Status Indicator	Proposed CY 2011 APC	Proposed CY 2011 Payment Rate

CY 2010 CPT Code	CY 2010 Long Descriptor	Proposed CY 2011 Status Indicator	Proposed CY 2011 APC	Proposed CY 2011 Payment Rate
0223T	Acoustic cardiography, including automated analysis of combined acoustic and electrical intervals; single, with interpretation and report	S	0099	$26.49
0224T	Multiple, including serial trended analysis and limited reprogramming of device parameter - AV or VV delays only, with interpretation and report	S	0690	$23.57
0225T	Multiple, including serial trended analysis and limited reprogramming of device parameter - AV and VV delays, with interpretation and report	S	0690	$23.57
0226T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed	X	0340	$45.00
0227T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)	T	0146	$388.30
0228T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; single level	T	0207	$484.15
0229T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; each additional level (List separately in addition to code for primary procedure)	T	0206	$250.28
0230T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level	T	0207	$484.15
0231T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; each additional level (List separately in addition to code for primary procedure)	T	0206	$250.28
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed	X	0340	$45.00
0233T	Skin advanced glycation endproducts (AGE) measurement by multi-wavelength fluorescent spectroscopy	A	NA	NA
90664	Influenza virus vaccine, pandemic formulation, live, for intranasal use	E	NA	NA
90666	Influenza virus vaccine, pandemic formulation, split virus, preservative free, for intramuscular use	E	NA	NA
90667	Influenza virus vaccine, pandemic formulation, split virus, adjuvanted, for intramuscular use	E	NA	NA

CY 2010 CPT Code	CY 2010 Long Descriptor	Proposed CY 2011 Status Indicator	Proposed CY 2011 APC	Proposed CY 2011 Payment Rate
90668	Influenza virus vaccine, pandemic formulation, split virus, for intramuscular use	E	NA	NA

For CY 2011, we are soliciting public comments on the proposed status indicators and the proposed APC assignments and payment rates, if applicable, for the Level II HCPCS codes and the Category I vaccine codes and Category III CPT codes that are newly recognized in April or July 2010 through the respective OPPS quarterly update CRs. These codes are listed in Tables 13, 14, and 15 of this proposed rule. We are proposing to finalize their status indicators and their APC assignments and payment rates, if applicable, in the CY 2011 OPPS/ASC final rule with comment period. Because the July 2010 OPPS quarterly update CR is issued close to the publication of this proposed rule, the Level II HCPCS codes and the Category I vaccine and Category III CPT codes implemented through the July 2010 OPPS quarterly update CR could not be included in Addendum B to this proposed rule, but these codes are listed in Tables 14 and 15, respectively. We are proposing to incorporate them into Addendum B to the CY 2011 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 2010 OPPS update CR and displayed in Table 13 are included in Addendum B to this proposed rule, where their proposed CY 2011 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 2011 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 2011. Specifically, for CY 2011, we are proposing to include in Addendum B to the CY 2011 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2011 (including those Category I vaccine and Category III CPT codes that were released by the AMA in July 2010) that

would be incorporated in the January 2011 OPPS quarterly update CR and the new Level II HCPCS codes, effective October 1, 2010, or January 1, 2011, that would be released by CMS in its October 2010 and January 2011 OPPS quarterly update CRs. These codes would be flagged with comment indicator "NI" in Addendum B to the CY 2011 OPPS/ASC final rule with comment period to indicate that we have assigned them an interim OPPS payment status. Their status indicators and their APC assignments and payment rates, if applicable, would be open to public comment in the CY 2011 OPPS/ASC final rule with comment period and would be finalized 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 (and so that an implantable item is classified to the group that includes the services to which the item relates). In accordance with these provisions, we developed a grouping classification system, referred to as APCs, as set forth in §419.31 of the regulations. We use Level I and Level II HCPCS codes and descriptors 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, as well as medical visits. 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 2010 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 (that is, where the Level 3 hospital clinic visit CPT code of five levels of hospital clinic visits is assigned), 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 not less often than annually and revise the groups , the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of the BBRA, 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 2011 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. 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 2011.

During the APC Panel's February 2010 meeting, we presented median cost and utilization data for services furnished during the period of January 1, 2009 through September 30, 2009, 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 2011 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 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 2011 included in this proposed rule are related to changes in median costs of services that were observed in the CY 2009 claims data newly available for CY 2011 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 2011.

Addendum B to this proposed rule 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 2010 Addendum B update (via Transmittal 1924, Change Request 6857, dated February 26, 2010).

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 2011 based on the APC Panel recommendations 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, and the use of CY 2009 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)
- 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 16 of this proposed rule lists 17 APCs that we are proposing to exempt from the 2 times rule for CY 2011 based on the criteria cited above. 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 2009 claims data used to determine the APC payment rates that we are proposing for CY 2011. The 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 16.—PROPOSED APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2011

Proposed CY 2011 APC	Proposed CY 2011 APC Title
0051	Level III Musculoskeletal Procedures Except Hand and Foot
0057	Bunion Procedures
0058	Level I Strapping and Cast Application
0080	Diagnostic Cardiac Catheterization
0105	Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices
0138	Level II Closed Treatment Fracture Finger/Toe/Trunk
0142	Small Intestine Endoscopy
0173	Level II Partial Hospitalization (4 or more services)
0235	Level I Posterior Segment Eye Procedures
0245	Level I Cataract Procedures without IOL Insert
0303	Treatment Device Construction
0325	Group Psychotherapy
0340	Minor Ancillary Procedures
0344	Level IV Pathology
0432	Health and Behavior Services

Proposed CY 2011 APC	Proposed CY 2011 APC Title
0604	Level 1 Hospital Clinic Visits
0664	Level I Proton Beam Radiation Therapy

C. New Technology APCs

1. Background

In the November 30, 2001 final rule (66 FR 59903), we finalized changes to the time period a service was eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to a clinically appropriate 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 through $2,000 in increments of $100, and from $2,000 through $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 again 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 hospital inpatient market basket. 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 providers to make their decisions regarding the acquisition of high cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCS, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our

OPPS payments remain appropriate for procedures as they transition into mainstream medical practice.

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

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

Consistent with our current policy, for CY 2011, we are proposing to retain services within New Technology APC groups until we gather sufficient 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 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.

Table 17 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 2011. For CY 2010, there are four services described by a HCPCS G-code receiving payment through a New Technology APC. Specifically, HCPCS code G0416 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1-20 specimens), is assigned to New Technology APC 1505 (New Technology - Level V ($300 - $400)); HCPCS code G0417 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21-40 specimens), is assigned to New Technology APC 1507 (New Technology - Level VII ($500 - $600)); 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 - $1000)); 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 ($1100 - $1200)). Based on the CY 2009 OPPS claims data available for this proposed rule, we believe that we have sufficient claims data to propose reassignment of HCPCS codes G0416 and G0417. Specifically, for HCPCS code G0416, our claims data show a median cost of approximately $113 based on 251 single claims out of 1,373 total claims for this service in CY 2009. For HCPCS code G0417, our claims data show a median cost of approximately $489 based on 5 single claims out of 135 total claims. We discuss our identification of single procedure claims, including “pseudo” single procedure claims, for ratesetting in section II.A.2. of this proposed rule. We believe we have sufficient claims data to propose the reassignment of HCPCS G-codes G0416 and G0417 to more

appropriate APCs for CY 2011. Therefore, for CY 2011, we are proposing to reassign these procedures to more appropriate APCs. Specifically, we are proposing to reassign HCPCS G-code G0416 from New Technology APC 1505 to clinical APC 0661 (Level V Pathology), which has an APC median cost of approximately $165, and HCPCS G-code G0417 from New Technology APC 1507 (New Technology – Level VII ($500 to $600)) to New Technology APC 1506 (New Technology - Level VI ($400 - $500)). We believe that HCPCS G-code G0416 is comparable clinically and with respect to the use of resources as other pathology services currently assigned to APC 0661. We also believe that HCPCS G-code G0417 would be more appropriately placed in New Technology APC 1506 in light of the median cost data available to us. Specifically, the HCPCS median cost of approximately $489 for HCPCS code G0417 closely aligns with the APC median cost of approximately $489 for APC 1506. We believe that HCPCS code G0417 would be more appropriately placed in APC 1506 based on clinical and resource considerations. These services and their proposed APC assignments are displayed in Table 17 below.

For CY 2011, we are proposing to continue the New Technology APC assignments for HCPCS G-codes G0418 and G0419, which isbased on our understanding of the clinical and cost characteristics of the procedures described by these HCPCS codes. We do not believe we have enough claims data to assign these codes to a different APC. Specifically, our claims data show no single claims, out of 29 total claims, for HCPCS code G0418. Similarly, our data show no single claims, out of 3 total claims, for HCPCS code G0419. While we believe that these services always will be low volume,

given the number of specimens being collected, we believe that we should continue their New Technology payments for another year to see if more claims data become available for HCPCS codes G0418 and G0419. Specifically, we are proposing to continue to assign HCPCS G-code G0418 to New Technology APC 1511 (New Technology - Level XI ($900 - $1,000)) and HCPCS G-code G0419 to New Technology APC 1513 (New Technology - Level XIII ($1,100 - $1,200)).

TABLE 17.—PROPOSED CY 2011 REASSIGNMENT OF NEW TECHNOLOGY PROCEDURES

CY 2010 HCPCS Code	CY 2010 Short Descriptor	CY 2010 SI	CY 2010 APC	Proposed CY 2011 SI	Proposed CY 2011 APC
G0416	Sat biopsy prostate 1-20 spc	S	1505	X	0661
G0417	Sat biopsy prostate 21-40	S	1507	S	1506

D. Proposed OPPS APC-Specific Policy: Skin Repair (APCs 0134 and 0135)

At the August 2009 APC Panel meeting, one public presenter requested that the APC Panel recommend that CMS reassign the Apligraf application CPT codes, specifically CPT codes 15340 (Tissue cultured allogeneic skin substitute; first 25 sq cm or less) and 15341 (Tissue cultured allogeneic skin substitute; each additional 25 sq cm, or part thereof), from APC 0134 (Level II Skin Repair) to APC 0135 (Level III Skin Repair). The same presenter requested that CMS continue to assign the Dermagraft application CPT codes, specifically CPT codes 15365 (Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children) and 15366 (Tissue cultured allogeneic dermal substitute, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or

each additional 1% of body area of infants and children, or part thereof), to APC 0134. The public presenter believed that the CY 2010 proposal to continue to assign both the Apligraf and the Dermagraft application CPT codes to APC 0134 would create a financial incentive favoring the Dermagraft application. Specifically, the presenter explained that CPT instructions allow the separate reporting of the CPT codes for site preparation and debridement when Dermagraft is applied, while the CPT instructions for Apligraf application codes specify that site preparation and debridement cannot be separately reported. The presenter believed that this reporting difference and the resulting expected differences in the associated application procedure costs could be addressed by assigning the Apligraf application CPT codes to a higher paying APC than the Dermagraft application CPT codes, instead of the same APC as CMS proposed for CY 2010.

During the discussion, the APC Panel members were provided with the historical information on the coding and APC assignments for the skin substitute application procedures assigned to APCs 0134 and 0135. Specifically, the Apligraf application CPT codes 15340 and 15341, the Dermagraft application CPT codes 15365 and 15366, as well as the Oasis application CPT codes 15430 (Acellular xenograft implant; first 100 sq cm or less, or 1% of body area of infants and children) and 15431 (Acellular xenograft implant; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof), were at one time assigned to the same APC level (Level II Skin Repair). However, because of violations of the two times rule, CMS reconfigured the

skin repair APCs and reassigned the Oasis application CPT codes 15430 and 15431 to APC 0135 (Level III Skin Repair) in CY 2008.

At the August 2009 APC Panel meeting, panel members debated whether the differences in sizes in each product's application CPT codes and the ability to bill separately for site preparation and debridement for Dermagraft application required different APC placement for any of the skin substitute application codes. We note that the long descriptors for the Apligraf application CPT codes 15340 and 15341 are scaled to "25 sq cm," whereas the Oasis application CPT codes 15430 and 15431 and the Dermagraft application CPT codes 15365 and 15366 are scaled to "100 sq cm." After review of median cost data from the CY 2008 hospital outpatient claims available at that time (those processed from January 1, 2008 through December 31, 2009), the APC Panel recommended that CMS continue to assign all six skin substitute application CPT codes to their existing APCs for CY 2010. In addition, because of the variable sizes associated with the skin repair application CPT codes, the Panel requested that CMS provide data at the next Panel meeting on the frequency of primary and add-on CPT codes billed for the Apligraf, Oasis, and Dermagraft applications in order to assess the variability in billing for the application of these products. In addition, because of the CPT instructions allowing site preparation and debridement to be reported separately only for the Dermagraft application, the Panel requested median cost data for site preparation and debridement.

We accepted the APC Panel's recommendation to continue to assign the skin repair CPT codes for the application of Apligraf, Oasis, and Dermagraft skin substitutes

to the same procedural APCs for CY 2010 as their CY 2009 assignments. As a result, we continued to assign the Apligraf application CPT codes 15340 and 15341 and the Dermagraft application CPT codes 15365 and 15366 to APC 0134 and assigned the Oasis application CPT codes 15430 and 15431 to APC 0135 for CY 2010.

At the February 2010 APC Panel meeting, CMS presented the results of the data requested at the August 2009 meeting to the APC Panel. In response to data on the frequency of primary and add-on CPT codes, based on our analysis of the available CY 2009 hospital outpatient claims data on frequency of primary and add-on CPT codes billed for the Apligraf, Oasis, and Dermagraft applications (claims processed from January 1 through September 30, 2009), we found that hospitals report the application of Apligraf with only the primary code (CPT code 15340) on 77 percent of claims, while the add-on CPT code 15341 is billed in addition to the primary code on another 23 percent of claims. Specifically, our data showed that for the Apligraf application, there were a total of 8,614 claims with only the primary CPT code 15340 reported, and 2,545 claims with the add-on CPT code 15341 also reported on the same date of service. We note that each unit of the add-on CPT code is paid at 50 percent of the payment for the primary code in addition to the full payment for the primary code. We also found in our analysis that, on claims with the Dermagraft and Oasis application CPT codes, hospitals report the primary code only in approximately 98 to 99 percent of the cases. In addition, in response to the request for data for site preparation and debridement that may be reported separately for the Dermagraft application, we found that approximately 87 percent of procedures for the application of Dermagraft were reported without debridement or site

preparation on the same day. Similarly, we found that the Apligraf and Oasis procedures were rarely reported with the site preparation or debridement CPT procedure codes on the same day. Specifically, we found that the CPT procedure code for the application of Apligraf was reported without site preparation or debridement in approximately 94 percent of these cases, and that the CPT procedure code for application of Oasis was reported without site preparation or debridement in approximately 95 percent of these cases. Our data analysis also showed that the CPT median costs for the Apligraf application CPT code 15340 and the Dermagraft application CPT code 15365 are very similar. Specifically, the CPT code-specific median cost of CPT code 15340 is approximately $234 for the Apligraf application and approximately $237 for CPT code 15365 for the Dermagraft application. In contrast, the CPT median cost for the Oasis application primary CPT code 15430 of approximately $299 is higher.

At the February 2010 APC Panel meeting, a public presenter again requested that the APC Panel recommend that CMS reassign the Apligraf application CPT codes 15340 and 15341 from APC 0134 to APC 0135. The presenter indicated that the additional payment for site preparation and debridement procedures that may be reported separately with the Dermagraft application can significantly affect the total payment for the procedure. The presenter also provided data on the use of each product in relation to the size of the wounds treated, and concluded that the size of the wound treated does not affect the resources used. After further review of the available CY 2009 hospital outpatient claims data, the APC Panel recommended that CPT codes 15340 and 15341 remain in APC 0134.

We are accepting the recommendation of the APC Panel and are proposing to continue to assign the CPT skin repair codes for the application of Apligraf, Dermagraft, and Oasis skin substitutes to the same procedural APCs as their CY 2010 assignments for CY 2011. We also are proposing to continue to pay separately for the Apligraf, Dermagraft, and Oasis products themselves in CY 2011. Specifically, we are proposing to continue to assign the Apligraf application CPT codes 15340 and 15341 and the Dermagraft application CPT codes 15365 and 15366 to APC 0134, with a proposed APC median cost of approximately $222. We are proposing to continue to assign the Oasis application CPT codes 15430 and 15431 to APC 0135, with a proposed APC median cost of approximately $325.

For CY 2011, we also are proposing to create two new Level II HCPCS G-codes to report the application of Apligraf or Dermagraft specific to the lower extremities in order to provide appropriate and consistent payment for these services as they are commonly furnished, consistent with the CY 2011 proposal for the MPFS. (We refer readers to the CY 2011 MPFS proposed rule for additional information regarding the MPFS proposal.) The proposed HCPCS codes are: GXXX1 (Application of tissue cultured allogeneic skin substitute or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; first 25 sq cm or less); and GXXX2 (Application of tissue cultured allogeneic skin or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; each additional 25 sq cm). As indicated in the HCPCS G-code descriptors, these codes would not allow separate reporting of CPT codes for site preparation or debridement. We believe the

descriptors of these proposed HCPCS G-codes more specifically reflect the characteristics of the application of Apligraf or Dermagraft to the lower limb so that reporting would result in more accurate cost data for OPPS ratesetting and, ultimately, more appropriate payment. Consistent with the proposed CY 2011 APC assignment for the Apligraf and Dermagraft application CPT codes, we are proposing to assign new HCPCS codes GXXX1 and GXXX2 to APC 0134, with a proposed APC median cost of approximately $222. We are specifically interested in public comment on the appropriateness of recognizing these proposed new HCPCS G-codes under the OPPS and their proposed APC assignments.

IV. Proposed OPPS Payment for Devices

A. Pass-Through Payments for Devices

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

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 dates for the category codes on the date on which a category is in effect. The date on which a 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 are no device categories eligible for pass-through payment, and there are no categories for which we would propose expiration of pass-through status in CY 2011. If we create new device categories for pass-through payment status during the remainder of CY 2010 or during 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.

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 2010 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) 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 also 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).

b. Proposed Policy

For CY 2011, we are proposing to continue our policy that the pass-through evaluation process and pass-through payment methodology for implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that are newly approved for pass-through status beginning on or after January 1, 2010, be the device pass-through process and payment methodology only. 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. We also 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)).

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 2011 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 did 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 2011 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 2011 device pass-through payment applications and by CMS in reviewing those applications.

In summary, for CY 2011, 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 rate-setting 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 rate-setting methodology for device-dependent APCs for CY 2011.

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 2011, we are proposing to continue to apply 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 rate-setting 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.

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 are proposing to continue to restrict the devices to which the APC payment adjustment would apply to a specific set of costly devices to ensure that the adjustment would not be triggered by the implantation of an inexpensive device whose cost would not constitute a significant proportion of the total payment rate for an APC. We continue to believe these criteria are appropriate because free devices and device credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the APC into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost.

We examined the offset amounts calculated from the CY 2011 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 applies in CY 2010 continue to meet the criteria for CY 2011, and to determine whether other APCs to which the policy does not apply in CY 2010 would meet the criteria for CY 2011. Based on the CY 2009 claims data available for this proposed rule, we are not proposing any changes to the APCs and devices to which this policy applies. Table 18 below lists the proposed APCs to which the payment adjustment policy for no cost/full credit and partial credit devices would apply in CY 2011 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 as shown in Table 18. Table 19 below lists the proposed devices to which this policy would apply in CY 2011. 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 2011, consistent with the three selection criteria discussed earlier in this section, based on the final CY 2009 claims data available for the CY 2011 OPPS/ASC final rule with comment period.

TABLE 18.—PROPOSED APCs TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY

Proposed CY 2011 APC	Proposed CY 2011 APC Title	Proposed CY 2011 Device Offset Percentage for No Cost/ Full Credit Case	Proposed CY 2011 Device Offset Percentage for Partial Credit Case
0039	Level I Implantation of Neurostimulator Generator	85%	43%
0040	Percutaneous Implantation of Neurostimulator Electrodes	56%	28%
0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes	63%	31%
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	70%	35%
0090	Insertion/Replacement of Pacemaker Pulse Generator	72%	36%
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes	46%	23%
0107	Insertion of Cardioverter-Defibrillator	88%	44%
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	87%	44%
0225	Implantation of Neurostimulator Electrodes, Cranial Nerve	78%	39%
0227	Implantation of Drug Infusion Device	81%	41%
0259	Level VII ENT Procedures	86%	43%
0315	Level II Implantation of Neurostimulator Generator	88%	44%
0385	Level I Prosthetic Urological Procedures	61%	30%
0386	Level II Prosthetic Urological Procedures	71%	36%
0418	Insertion of Left Ventricular Pacing Elect.	72%	36%
0425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
0648	Level IV Breast Surgery	45%	23%
0654	Insertion/Replacement of a	73%	37%

Proposed CY 2011 APC	Proposed CY 2011 APC Title	Proposed CY 2011 Device Offset Percentage for No Cost/ Full Credit Case	Proposed CY 2011 Device Offset Percentage for Partial Credit Case
	permanent dual chamber pacemaker		
0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	73%	37%
0680	Insertion of Patient Activated Event Recorders	71%	35%

TABLE 19.—PROPOSED DEVICES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY

CY 2010 Device HCPCS Code	CY 2010 Short Descriptor
C1721	AICD, dual chamber
C1722	AICD, single chamber
C1728	Cath, brachytx seed adm
C1764	Event recorder, cardiac
C1767	Generator, neurostim, imp
C1771	Rep dev, urinary, w/sling
C1772	Infusion pump, programmable
C1776	Joint device (implantable)
C1777	Lead, AICD, endo single coil
C1778	Lead, neurostimulator
C1779	Lead, pmkr, transvenous VDD
C1785	Pmkr, dual, rate-resp
C1786	Pmkr, single, rate-resp
C1789	Prosthesis, breast, imp
C1813	Prosthesis, penile, inflatab
C1815	Pros, urinary sph, imp
C1820	Generator, neuro rechg bat sys
C1881	Dialysis access system
C1882	AICD, other than sing/dual
C1891	Infusion pump, non-prog, perm
C1895	Lead, AICD, endo dual coil
C1896	Lead, AICD, non sing/dual
C1897	Lead, neurostim, test kit
C1898	Lead, pmkr, other than trans
C1899	Lead, pmkr/AICD combination
C1900	Lead coronary venous
C2619	Pmkr, dual, non rate-resp

CY 2010 Device HCPCS Code	CY 2010 Short Descriptor
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 biological agents. 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 biological agents and brachytherapy sources used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. For those drugs and biological agents 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 biological agents 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 at least 2 years but not more than 3 years after the product's first payment as a hospital outpatient service under Part B. Proposed CY 2011 pass-through drugs and biologicals and their designated APCs are assigned status indicator "G" in Addenda A and B to this proposed rule.

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.

This methodology for determining the pass-through payment amount is set forth in §419.64 of the regulations, which specifies 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 use of the average sales price (ASP) methodology as the basis for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act that are 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, wholesale acquisition cost (WAC), and 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.

As noted above, section 1833(t)(6)(D)(i) of the Act also states that if a drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, the payment rate is equal to the average price for the drug or biological for all competitive acquisition areas and the year established as calculated and adjusted by the Secretary. Section 1847B of the Act establishes the payment methodology for Medicare Part B drugs and biologicals under the competitive acquisition program (CAP). The Part B drug CAP was implemented on July 1, 2006, and included approximately 190 of the most common Part B drugs provided in the physician's office setting. As we noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68633), the Part B drug CAP program was suspended beginning in CY 2009 (Medicare Learning Network (MLN) Matters Special Edition 0833, available via the Web site: http://www.medicare.gov). Therefore, there is no effective Part B drug CAP rate for

pass-through drugs and biologicals as of January 1, 2009. Consistent with what we indicated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60466), if the program is reinstituted during CY 2011 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 drugs and biologicals with pass-through status.

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 that the OPPS pass-through payment estimate for drugs and biologicals to be $35.5 million. Our proposed OPPS pass-through payment estimate for drugs and biologicals in CY 2011 is $15 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 2010

We are proposing that the pass-through status of 18 drugs and biologicals would expire on December 31, 2010, as listed in Table 20 of this proposed rule. 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, 2010. These items were approved for pass-through status on or before January 1, 2009. 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 $70 for CY 2011), as discussed further in section V.B.2 of this proposed rule. If the drug's or biological's estimated per day cost is less than or equal to the applicable OPPS drug packaging threshold, we would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we would provide separate payment at the applicable relative ASP-based payment amount (which is proposed at ASP+6 percent for CY 2011, 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 20.—PROPOSED DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS WOULD EXPIRE DECEMBER 31, 2010

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 SI	Proposed CY 2011 APC
A9581	Injection, gadoxetate disodium, 1 ml	N	N/A
C9248	Injection, clevidipien butyrate, 1 mg	K	9248
C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter	N	N/A
C9358	Dermal substitute, native, non-denatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters	K	9358
C9359	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5 cc	N	N/A
J1267	Injection, doripenem, 10 mg	N	N/A
J1453	Injection, fosaprepitant, 1 mg	K	9242
J1459	Injection, immune globulin (privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg	K	1214
J1571	Injection, hepatitis b immune globulin (hepagam b), intramuscular, 0.5 ml	K	0946
J1573	Injection, hepatitis B immune globulin (Hepagam B), intravenous, 0.5ml	K	1138
J1953	Injection, levetiracetam, 10 mg	N	N/A
J2785	Injection, regadenoson, 0.1 mg	K	9244
J2796	Injection,romiplostim, 10 micrograms	K	9245
J9033	Injection, bendamustine hcl, 1 mg	K	9243
J9207	Injection, ixabepilone, 1 mg	K	9240
J9225	Histrelin implant (vantas), 50 mg	K	1711
J9226	Histrelin implant (supprelin la), 50 mg	K	1142
Q4114	Dermal substitute, granulated cross-linked collagen and glycosaminoglycan matrix (Flowable Wound Matrix), 1 cc	K	1251

3. Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Status in CY 2011

We are proposing to continue pass-through status in CY 2011 for 31 drugs and biologicals. None of these products will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2010. These items, which

were approved for pass-through status between April 1, 2009 and July 1, 2010, are listed in Table 21 below. The APCs and HCPCS codes for these drugs and biologicals were assigned status indicator "G" in Addenda A and B to this proposed rule.

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 continue to provide payment for drugs and biologicals with pass-through status at a rate of ASP+6 percent in CY 2011, the amount that drugs and biologicals receive under section 1842(o) of the Act. Thus, for CY 2011, 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 2011. We are proposing that a $0.00 pass-through payment amount would be paid for most pass-through drugs and biologicals under the CY 2011 OPPS because the difference between the amount authorized under Section 1842 (o) which is ASP+6 percent and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate,

proposed at ASP+6 percent is $0. In the case of pass-through contrast agents, diagnostic radiopharmaceuticals, and implantable biologicals, 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.

In addition, we are proposing to continue to update pass-through payment rates on a quarterly basis on the CMS Web site during CY 2011 if later quarter ASP submission (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 2011, and a drug or biological that has been granted pass-through status for CY 2011 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 appropriate 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 2011, as is consistent with our CY 2010 policy for diagnostic 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 and, therefore, if a diagnostic or

therapeutic radiopharmaceutical receives pass-through status during CY 2011, we are proposing to follow the standard ASP methodology to determine its pass-through payment rate that drugs receive under section 1842 (o) of the Act, that 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 3 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, and we are proposing to continue the packaging of these items, regardless of their per day cost, in CY 2011. 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)) or for an implantable

biological (which we to consider to be a device for all payment purposes as discussed in sections V.A.4. and V.B.2.d. of the CY 2010 OPPS/ASC final rule with comment period (74 FR 60458)) 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 or device APC offset amount for the associated clinical APC in which the drug or biological is utilized. The calculation of the "policy-packaged" drug and device APC offset amounts are described in more detail in sections 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 2010, we are proposing to continue to set the associated copayment amount for pass-through diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals that would otherwise be packaged if the item did not have pass-through status to zero for CY 2011. The separate OPPS payment to a hospital for the pass-through diagnostic radiopharmaceutical, contrast agent, or implantable biological, 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.

TABLE 21.—PROPOSED DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2011

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 SI	Proposed CY 2011 APC
A9582	Iodine I-123 iobenguane, diagnostic, per study dose, up to 15 millicuries	G	9247
A9583	Injection, gadofosveset trisodium, 1 ml	G	1299
C9250	Human plasma fibrin sealant, vapor-heated, solvent-detergent (Artiss), 2ml	G	9250
C9255	Injection, paliperidone palmitate, 1 mg	G	9255
C9256	Injection, dexamethasone intravitreal implant, 0.1 mg	G	9256
C9258	Injection, telavancin, 10 mg	G	9258
C9259	Injection, pralatrexate, 1 mg	G	9259
C9260	Injection, ofatumumab, 10 mg	G	9260
C9261	Injection, ustekinumab, 1 mg	G	9261
C9263	Injection, ecallantide, 1 mg	G	9263
C9264	Injection, tocilizumab, 1 mg	G	9624
C9265	Injection, romidepsin, 1 mg	G	9625
C9266	Injection, collagenase clostridium histolyticum, 0.1 mg	G	9266
C9267	Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO	G	9267
C9268	Capsaicin, patch, 10cm2	G	9268
C9360	Dermal substitute, native, non-denatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 square centimeters	G	9360
C9361	Collagen matrix nerve wrap (NeuroMend Collagen Nerve Wrap), per 0.5 centimeter length	G	9361
C9362	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc	G	9362
C9363	Skin substitute, Integra Meshed Bilayer Wound Matrix, per square centimeter	G	9363
C9364	Porcine implant, Permacol, per square centimeter	G	9364
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	G	9367
J0598	Injection, C1 esterase inhibitor (human), 10 units	G	9251

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 SI	Proposed CY 2011 APC
J0641	Injection, levoleucovorin calcium, 0.5 mg	G	1236
J0718	Injection, certolizumab pegol, 1 mg	G	9249
J1680	Injection, human fibrinogen concentrate, 100 mg	G	1290
J2562	Injection, plerixafor, 1 mg	G	9252
J8705	Topotecan, oral, 0.25 mg	G	1238
J9155	Injection, degarelix, 1 mg	G	1296
J9328	Injection, temozolomide, 1 mg	G	9253
Q0138	Injection, Ferumoxytol, for treatment of iron deficiency anemia, 1 mg	G	1297
Q2025	Fludarabine phosphate, oral, 1 mg	G	9262

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 2011, 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) (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 A9582 (Iobenguane, I-123, diagnostic, per study dose, up to 10 millicuries). HCPCS code A9582 was granted pass-through status beginning April 1, 2009 and will continue on pass-through status in CY 2011. 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, new pass-through diagnostic radiopharmaceuticals will be paid at ASP+6 percent, while those without ASP information will be paid at WAC+6 percent or, if WAC is not available, payment will be based on 95 percent of the product's most recently published AWP.

As a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the payment for pass-through radiopharmaceuticals an amount that reflects 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.

The Integrated Outpatient Code Editor processes claims for nuclear medicine procedures only when they are performed with a radiolabeled product. Therefore, the radiolabeled product edits in the Integrated Outpatient Code Editor require a hospital to report a diagnostic radiopharmaceutical with a nuclear medicine scan in order to receive payment for the nuclear medicine scan. We have received questions from hospitals on how to bill for a nuclear medicine scan when they receive a diagnostic radiopharmaceutical free of charge or with full credit. Currently, if a hospital receives a diagnostic radiopharmaceutical free of charge or with full credit and uses it to provide a nuclear medicine scan, the hospital could choose not to bill for both the nuclear medicine

scan and the diagnostic radiopharmaceutical in order to bypass the radiolabeled product edits, but the hospital clearly would not receive OPPS payment for the scan or the diagnostic radiopharmaceutical. The hospital also could report the diagnostic radiopharmaceutical with the nuclear medicine scan and receive an APC payment that includes payment for the diagnostic radiopharmaceutical, but this would lead to inaccurate billing and incorrect payment. This is because the OPPS should not pay for a free item. We believe neither of the above alternatives is satisfactory.

In order to ensure that the OPPS is making appropriate and equitable payments under such circumstances and that a hospital can comply with the required radiolabeled product edits, we are proposing for CY 2011 to instruct hospitals to report the "FB" modifier on the line with the procedure code for the nuclear medicine scan in the APCs listed in Table E3 in which the no cost/full credit diagnostic radiopharmaceutical is used. Modifier -FB is "Item Provided Without Cost to Provider, Supplier or Practitioner, or Credit Received for Replacement Device (Examples, but not Limited to: Covered Under Warranty, Replaced Due to Defect, Free Samples)." Although this modifier is specific to devices, it captures the concept of the hospital receiving a key component of the service without cost. In cases in which the diagnostic radiopharmaceutical is furnished without cost or with full credit, we are proposing to instruct the hospital to report a token charge of less than $1.01. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the "FB" payment adjustment policies (72 FR 66743 through 66749). We are proposing that when a hospital bills an -FB with the nuclear medicine scan, the payment amount for procedures in the APCs listed in

Table 20 would be reduced by the full "policy-packaged" offset amount appropriate for diagnostic radiopharmaceuticals. As discussed in our CY 2009 OPPS/ASC final rule with comment period, the "policy packaged" offset amount that we calculate estimates 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). As in our offset policy, discussed below, we believe it is appropriate to remove the "policy packaged" offset amount from payment for a nuclear medicine scan with a diagnostic radiopharmaceutical received at no cost or full credit which is billed using one of the APCs appearing in Table 22 below because it represents the portion of the APC payment attributable to diagnostic radiopharmaceuticals used in the performance of a nuclear medicine scan. Using the -FB modifier with radiolabeled products will allow the hospital to bill accurately for a diagnostic radiopharmaceutical received free of charge and will allow the hospital to comply with the radiolabeled product edits to ensure appropriate payment.

At this time, we are not proposing to recognize modifier FC, which is defined as "Partial credit received for replaced device," because we were unsure of the circumstances in which hospitals would receive a diagnostic radiopharmaceutical at reduced cost to replace a previously provided diagnostic radiopharmaceutical. We invite public comment on when a diagnostic radiopharmaceutical is provided for a significantly reduced price and whether the "FC" modifier is appropriate for radiolabeled products.

We will continue to post annually on the CMS Web site at http://www.cms.gov/HospitalOutpatientPPS, a file that contains the APC offset amounts that would be used for that year for purposes of both evaluating cost significance for candidate pass-through device categories and drugs and biologicals, including diagnostic radiopharmaceuticals, 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, including implantable biologicals; "policy-packaged" drugs, including diagnostic radiopharmaceuticals and contrast agents; and "threshold-packaged" drugs and biologicals, which are all other drugs, therapeutic radiopharmaceuticals, and nonimplantable biologicals.

Table 22 below displays the proposed APCs to which nuclear medicine procedures would be assigned in CY 2011 and for which we expect that an APC offset could be applicable in the case of new diagnostic radiopharmaceuticals with pass-through status.

TABLE 22.—PROPOSED APCs TO WHICH NUCLEAR MEDICINE PROCEDURES WOULD BE ASSIGNED FOR CY 2011

Proposed CY 2011 APC	Proposed CY 2011 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.
0393	Hematologic Processing & Studies.
0394	Hepatobiliary Imaging.

Proposed CY 2011 APC	Proposed CY 2011 APC Title
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

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) (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 A9583 (Injection, gadoxetate disodium, per ml). HCPCS code A9583 was granted pass-through status beginning January 1, 2010, and will continue with pass-through status in CY 2011. 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, for CY 2011 we are proposing 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 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). As discussed above, 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 post annually on the CMS Web site at http://www.cms.gov/HospitalOutpatientPPS, a file that contains the APC offset amounts that would 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 agent 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 20 above, and these APCs are displayed in Table 23 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 2011, 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 23, 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 23.--APCs TO WHICH A CONTRAST AGENT OFFSET MAY BE APPLICABLE FOR CY 2011

Proposed CY 2011 APC	Proposed CY 2011 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.

Proposed CY 2011 APC	Proposed CY 2011 APC Title
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.
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 2010 OPPS, we currently pay for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status in one of two ways: packaged payment into the payment for the associated service; or 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, as added by section 621(a)(2) of Pub. L. 108-173, 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. 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, and our proposed approach for CY 2011 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 fourth quarter moving average Producer Price Index (PPI) levels for prescription preparations 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.

Following the CY 2007 methodology, for CY 2011, we used updated fourth quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2011 and again rounded the resulting dollar amount ($70.64) to the nearest $5 increment, which yielded a figure of $70. In performing this calculation, we used the most up-to-date forecasted, quarterly PPI estimates from CMS' Office of the Actuary (OACT). 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 2011 of $70. (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 2011 packaging status, for this proposed rule, we calculated the per day cost of all drugs 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 2011 as discussed in section V.B.2.d. of this

proposed rule), nonimplantable biologicals, and therapeutic radiopharmaceuticals (collectively called "threshold-packaged" drugs) that had a HCPCS code in CY 2009 and were paid (via packaged or separate payment) under the OPPS, using CY 2009 claims data processed before January 1, 2010. In order to calculate the per day costs for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2011, 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 2011 proposed rule per day costs, we used an estimated payment rate for each drug and nonimplantable biological HCPCS code of ASP+6 percent (which is the payment rate we are proposing for separately payable drugs and nonimplantable biologicals in CY 2011, 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 2009 (data that were used for payment purposes in the physician's office setting, effective April 1, 2010) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2011, we are proposing to use payment rates based on the ASP data from the fourth quarter of CY 2009 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule because these are the most recent data available for use at the time of development of this proposed rule. These data are also the basis for drug payments in the physician's office setting, effective April 1, 2010. 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 2009 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 $70 and identified items with a per day cost greater than $70 as separately payable. Consistent with our past practice, we crosswalked historical OPPS claims data from the CY 2009 HCPCS codes that were reported to the CY 2010 HCPCS codes that we displayed in Addendum B to this proposed rule for payment in CY 2011.

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 are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and nonimplantable biologicals in the CY 2011 OPPS/ASC final rule with comment period, we are proposing to use ASP data from the first quarter of CY 2010, 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, 2010, along with updated hospital claims data from CY 2009. We note that we also would use these data for budget neutrality estimates and impact analyses for the CY 2011 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 that final rule with comment period would be based on ASP data from the second

quarter of CY 2010, which are the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2010. These rates would then be updated in the January 2011 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2011. For items that do not currently have an ASP-based payment rate, we would recalculate their mean unit cost from all of the CY 2009 claims data and updated cost report information available for the CY 2011 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 the CY 2011 OPPS/ASC final rule with comment period using the updated data may be different from the same drug HCPCS code's packaging status determined based on the data used for this proposed rule. Under such circumstances, we are proposing to continue 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 CY 2011 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2010. Specifically, we are proposing for CY 2011 to apply the following policies to these HCPCS codes for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals whose relationship to the $70 drug packaging threshold changes based on the final updated data:

- HCPCS codes for drugs and nonimplantable biologicals that were paid separately in CY 2010 and that were proposed for separate payment in CY 2011, and then

have per day costs equal to or less than $70, based on the updated ASPs and hospital claims data used for the CY 2011 final rule with comment period, would continue to receive separate payment in CY 2011.

- HCPCS codes for drugs and nonimplantable biologicals that were packaged in CY 2010 and that were proposed for separate payment in CY 2011, and then have per day costs equal to or less than $70, based on the updated ASPs and hospital claims data used for the CY 2011 final rule with comment period, would remain packaged in CY 2011.

- HCPCS codes for drugs and nonimplantable biologicals for which we proposed packaged payment in CY 2011 but then have per day costs greater than $70, based on the updated ASPs and hospital claims data used for the CY 2011 final rule with comment period, would receive separate payment in CY 2011. In the CY 2010 OPPS/ASC final rule (74 FR 60485 through 60489), we implemented a policy to treat oral and injectable forms of 5-HT3 antiemetics comparable to all other threshold packaged drugs, nonimplantable biologicals, and therapeutic radiohpharmaceuticals under our standard packaging methodology of packaging drugs with a per day cost less than $70. For CY 2011, we are proposing to continue our policy of not exempting these 5-HT3 antiemetic products from our standard packaging methodology and to package payment for all of the 5-HT3 antiemetics except palonosetron hydrochloride, consistent with their estimated per day costs from the CY 2009 claims data.

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 new code(s)' packaged or separately payable status. 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 2011, 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 2011.

For CY 2011, 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 2009 claims data and our pricing information at ASP+6 percent across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. HCPCS codes J9093 (cyclophosphamide, lyophilized, 100 mg), J9094 (cyclophosphamide, lyophilized, 200 mg), J9095 (cyclophosphamide, lyophilized, 500 mg), J9096 (cyclophosphamide, lyophilized, 1g), and J9097 (cyclophosphamide, lyophilized, 2g) did not have pricing information available for the ASP methodology and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from fourth quarter CY 2009 claims data to make the packaging determinations for these drugs. For all other drugs and biologicals that have HCPCS codes describing different dosages, we then multiplied the weighted average ASP+6 percent or mean unit cost 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 $70 (whereupon all HCPCS codes for the same drug or biological would be

packaged) or greater than $70 (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 24.

TABLE 24.—HCPCS CODES TO WHICH THE PROPOSED CY 2011 DRUG-SPECFIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 SI
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1380	Injection, estradiol valerate, up to 10 mg	N
J0970	Injection, estradiol valerate, up to 40 mg	N
J1390	Injection, estradiol valerate, up to 20 mg	N
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
J1470	Injection, gamma globulin, intramuscular 2 cc	K
J1480	Injection, gamma globulin, intramuscular 3 cc	K
J1490	Injection, gamma globulin, intramuscular 4 cc	K
J1500	Injection, gamma globulin, intramuscular 5 cc	K
J1510	Injection, gamma globulin, intramuscular 6 cc	K
J1520	Injection, gamma globulin, intramuscular 7 cc	K
J1530	Injection, gamma globulin, intramuscular 8 cc	K
J1540	Injection, gamma globulin, intramuscular 9 cc	K
J1550	Injection, gamma globulin, intramuscular 10 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
J2320	Injection, nandrolone decanoate, up to 50 mg	K
J2321	Injection, nandrolone decanoate, up to 100 mg	K
J2322	Injection, nandrolone decanoate, up to 200 mg	K

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 SI
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	K
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	K
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3120	Injection, testosterone enanthate, up to 100 mg	N
J3130	Injection, testosterone enanthate, up to 200 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7050	Infusion, normal saline solution , 250 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7030	Infusion, normal saline solution , 1000 cc	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	K
J8521	Capecitabine, oral, 500 mg	K
J9060	Cisplatin, powder or solution, per 10 mg	N
J9062	Cisplatin, 50 mg	N
J9070	Cyclophosphamide, 100 mg	N
J9080	Cyclophosphamide, 200 mg	N
J9090	Cyclophosphamide, 500 mg	N
J9091	Injection, cyclophosphamide, 1.0 gram	N
J9092	Cyclophosphamide, 2.0 gram	N
J9093	Cyclophosphamide, lyophilized, 100 mg	N
J9094	Cyclophosphamide, lyophilized, 200 mg	N
J9095	Cyclophosphamide, lyophilized, 500 mg	N
J9096	Cyclophosphamide, lyophilized, 1g	N
J9097	Cyclophosphamide, lyophilized, 2g	N
J9100	Injection, cytarabine, 100 mg	N
J9110	Injection, cytarabine, 500 mg	N
J9130	Dacarbazine, 100 mg	N
J9140	Injection, dacarbazine, 200 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N
J9280	Mitomycin, 5 mg	K
J9290	Mitomycin, 20 mg	K
J9291	Mitomycin, 40 mg	K
J9370	Vincristine sulfate, 1 mg	N
J9375	Vincristine sulfate, 2 mg	N
J9380	Vincristine sulfate, 5 mg	N

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 SI
Q0164	Prochlorperazine maleate, 5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour 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 anit0emetic 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 anit0emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0169	Promethazine hydrochloride, 12.5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0170	Promethazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0171	Chlorpromazine hydrochloride, 10 mg, oral, FDA approved prescription antiemetic, for use as a complete therapeutic substitute for an IV antiemetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen	N
Q0172	Chlorpromazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of 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

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 SI
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 exeed 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 to 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 statutory requirement that we must pay separately for drugs and biologicals for which the per day cost exceeds $50 under section 1833(t)(16)(B) of the Act 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 2011. 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 2011. 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 contrast 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 (73 FR 68634), we began packaging the payment for all nonpass-through implantable biologicals into payment for the associated surgical procedure. Because implantable biologicals may sometimes substitute for nonbiological devices, we noted that if we were to provide separate payment for implantable biologicals without pass-through status, we would potentially be providing duplicate device payment, both through the packaged nonbiological device cost already included in the surgical procedure's payment and separate biological payment. We concluded that we saw no basis for treating implantable biological and nonbiological devices without pass-through

status differently for OPPS payment purposes because both are integral to and supportive of the separately paid surgical procedures in which either may be used. Therefore, 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 packages 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, known as devices. For CY 2011, 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, referred to as devices. In accordance with this proposal, two of the products with expiring pass-through status for CY 2011 are biologicals that are solely surgically implanted according to their FDA-approved indications. These products are described by HCPCS codes C9356 (Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter) and C9359 (Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5 cc). Like the two implantable biologicals with expiring pass-through status in CY 2010 that were discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60459 through 60499), we believe that the two biologicals specified above with expiring pass-through status for CY 2011 differ from other biologicals paid under the OPPS in that they specifically function as surgically

implanted devices. As a result of the CY 2010 packaged payment methodology for all nonpass-through implantable biologicals, we are proposing to package payment for HCPCS codes C9356 and C9359 and assign them status indicator "N" for CY 2011. 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 2011. 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. 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 pursuant to ASP+6 percent pursuant to section 1842(o) of the Act 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

to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for them. 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), 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 which 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 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 the best 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.

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. 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, and we also 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 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 to us 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 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 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 cost of coded drugs and biologicals that is 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 CY 2010 final rule data would occur only from coded packaged drugs and biologicals with an ASP to separately payable drugs and biologicals, thereby maintaining the estimated total cost of drugs and biologicals.

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 on the claims and ASP for the same drugs), 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 35328). We stated 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 2008 claims data would represent the most accurate redistribution of pharmacy overhead cost. We included a discussion of indirect overhead costs, such as administrative and general costs, capital costs, staff benefits, and other facility costs that do not vary across drugs, and direct overhead costs, including 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. We presented analyses that modeled the redistribution of overhead costs in the packaged drugs to all drugs and biologicals based on overhead relative weights derived from industry and from MedPAC's recommended overhead relative weights and by assigning each drug, both packaged and separately paid, to a category of overhead complexity. Analyses relying on both sets of weights suggest

that indirect costs are a sizable component of the overhead costs associated with all drugs and biologicals (74 FR 60505 to 60508).

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 payment rate for separately payable drugs and biologicals of ASP+4 percent. Thus, we proposed a pharmacy overhead adjustment for separately payable drugs and biologicals in CY 2010 that would result in their payment at ASP+4 percent. Redistributing $150 million represented a reduction in cost of coded packaged drug 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 340B hospitals would be paid the same amounts for separately payable drugs and biologicals as hospitals that do not participate in the 340B program. 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.

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 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 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 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. With regard to uncoded packaged drug costs, we redistributed $50 million and stated that we could not know the amount of overhead associated with these drugs without making significant further assumptions about the amount of pharmacy overhead cost associated with the drugs and biologicals captured by these uncoded packaged drug costs. 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).

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 2011. 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. 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, payment for most Medicare 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 drugs (drugs furnished incident to a physician's service), DME drugs (drugs furnished under the durable medical equipment benefit), and drugs specifically covered by statute (certain oral anti-cancer and immunosuppressive drugs). In addition, 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 both the average hospital acquisition cost that the statute requires for payment of SCODs and the associated pharmacy overhead cost to establish a combined payment rate for acquisition cost and pharmacy overhead. Until 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.

However, for the CY 2010 OPPS, we revised the standard methodology to include an adjustment for pharmacy overhead. We acknowledged 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 are being attributed to packaged drugs and biologicals that are likely pharmacy overhead costs for separately payable drugs.

For this CY 2011 OPPS/ASC proposed rule, using our standard methodology for determining the total cost of separately payable drugs in our CY 2009 claims data and comparing 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, we determined that the total payment for separately payable drugs (status indicators "K" and "G"), including acquisition and pharmacy overhead costs, is ASP+0 percent, which also would be the ASP-based payment rate under the standard methodology that we established in CY 2006. Additionally, we determined that the total aggregate cost for packaged drugs with a HCPCS code for which manufacturers report ASP data (status indicator "N"), including acquisition and pharmacy overhead costs, is equivalent to ASP+283 percent. Finally, we determined that the total cost for both packaged drugs with a HCPCS code and separately payable drugs (status indicators "N", "K" and "G") for which we also have ASP data, including acquisition and pharmacy overhead costs, is ASP+14 percent. Table 25 below displays our findings with regard to the percentage of ASP in comparison to the cost for packaged coded drugs and for separately payable coded drugs before application of the overhead adjustment methodology.

TABLE 25.—CY 2011 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 C /column B)	ASP+X Percent
Uncoded packaged pharmacy revenue code costs	Unknown	$623	NA	NA
Coded Packaged Drugs and Biologicals with a reported ASP	$155	$593	3.83	ASP+283
Separately Payable Drugs and Biologicals with a reported ASP	$2,951	$2,939	1.00	ASP+0
All Coded Drugs and Biologicals with a reported ASP	$3,105	$3,532	1.14	ASP+14

*Total April 2010 ASP dollars (ASP multiplied by drug or biological units in CY 2009 claims) for drugs and biologicals with a HCPCS code and ASP information.
**Total cost in the CY 2009 claims data for drugs and biologicals.

We believe 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 believe payment at ASP + 0 percent for such costs may not be sufficient. We also acknowledge that ASP +283 percent may overstate the combined acquisition and pharmacy overhead cost of packaged drugs and biologicals. Therefore, for CY 2011, we are proposing to continue our CY 2010 pharmacy overhead adjustment

methodology. We are proposing to redistribute $150 million from the pharmacy overhead cost of coded packaged drugs and biologicals with reported ASP data and to redistribute $50 million from the cost of uncoded packaged drugs and biologicals without an ASP, for a total redistribution of $200 million in drug cost from the cost of coded and uncoded packaged drugs to the cost of separately payable drugs, as we did for the CY 2010 final rule. We estimate the overhead cost for coded packaged drugs to be $438 million ($593 million in total cost for coded packaged drugs and biologicals with a reported ASP less $155 million in total ASP dollars for coded packaged drugs and biologicals with a reported ASP). Similar to the CY 2010 proposal, we are proposing 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 continue to believe that redistributing $200 million from packaged to separately payable drugs and biologicals is an appropriate redistribution of pharmacy overhead costs to address any charge compression in the standard methodology. This would result in a proposed CY 2011 payment rate for separately payable drugs and biologicals of ASP+6 percent. We emphasize that we are proposing a pharmacy overhead adjustment methodology based on a redistribution of overhead cost and that our proposal for payment at ASP+6 percent is a coincidental outcome of the proposed methodology to redistribute $200 million from packaged drugs to separately payable drugs. We are not proposing payment of ASP+6 percent for separately payable drugs as an alternative to payment of average acquisition costs based on a survey under section 1833(t)(14)(A)(iii)(I) of the Act. We continue to believe that

the average sales price information collected under section 1847A (b)(1)(A) of the Act and our hospital claims data is a suitable proxy for the acquisition cost data. For a full explanation of our rationale for using ASP data and our hospital claims data as a suitable proxy for acquisition cost data we refer readers to the CY2010 OPPS/ASC final rule with comment period (74 FR 60515). We further 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, from ASP+5 to ASP+4 for example. Therefore, it is possible that this proposed methodology would result in an ASP+X amount that is different from ASP+6.

As indicated in Table 25 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 propose to pay for separately payable drugs and biologicals at ASP+0 percent. However, because we are concerned about underpaying separately payable drugs and biologicals, we believe a pharmacy overhead adjustment using a redistribution methodology for determining the amount of payment for drugs and biologicals as we did for CY 2010 is appropriate. We believe the observed ASP+0 percent reflects some amount of charge compression and variability attributable to choice of a packaging threshold.

We continue to believe that the methodology to redistribute $200 million in drug overhead cost from packaged coded and uncoded drugs to separately payable drugs, while keeping the total cost of drugs 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, we are proposing to redistribute $200 million in drug overhead costs from coded and uncoded packaged drugs to separately payable drugs while keeping the total cost of drugs in the claims data constant. Table 26 presents the ASP+X amount after redistribution of $150 million from the estimated overhead of $438 million for coded packaged drugs with reported ASP data to separately payable drugs and biologicals and $50 million from uncoded packaged drug cost for which an estimate of overhead cannot be calculated, resulting in a total redistribution of $200 million in cost from packaged drugs and biologicals to separately payable drugs and biologicals.

TABLE 26.— PROPOSED CY 2011 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 C /column B)	ASP+X Percent
Uncoded packaged pharmacy revenue code costs	Unknown	$548	NA	NA
Coded Packaged Drugs and Biologicals with a reported ASP	$155	$443	2.86	ASP+186
Separately Payable Drugs and Biologicals with a reported ASP	$2,951	$3,139	1.06	ASP+6
All Coded Drugs and Biologicals with a reported ASP	$3,105	$3,532	1.14	ASP+14

*Total April 2010 ASP dollars (ASP multiplied by drug or biological units in CY 2009 claims) for drugs and biologicals with a HCPCS code and ASP information.
**Total cost in the CY 2009 claims data for drugs and biologicals.

We generally received positive comments on our CY 2010 proposal to redistribute $150 million of drug cost from packaged drugs and biologicals to separately payable drugs and biologicals to establish their final combined payment level. The general comment we received on our pharmacy overhead adjustment methodology was that the amount of drug cost that should be redistributed should be greater, a sentiment reiterated at the February 2010 APC Panel meeting and discussed in greater detail below. Commenters and presenters to the APC Panel specifically argued that our CY 2010

proposal had not acknowledged the potential overhead cost available for redistribution in the uncoded packaged drugs.

We explain below our rationale for why we are not proposing to redistribute more cost from uncoded packaged drugs. Conversations with stakeholders and hospitals over the past year suggest that hospitals do not always report HCPCS codes for drugs for a variety of reasons including an internal practice not to code for packaged drugs, building the cost of the drugs into the associated procedure charge, lack of a HCPCS code for some drugs and biologicals, and purchased vendor billing software functionality that removes codes. A key premise of our pharmacy overhead adjustment redistribution methodology was our assessment of the amount of drug cost in the claims data above aggregate ASP available as "overhead" for redistribution. Knowing the specific HCPCS codes for packaged drugs and their associated ASP allows us to assess the differential between aggregate ASP and claim cost for packaged drugs and to assess the intensity of pharmacy overhead associated with these drugs. The inability to know which drugs are captured by uncoded drug charges on a claim is challenging because we cannot know what is being charged or what the overhead complexity might be. Further, we understand that there is wide variation in how hospitals set charges for items and services in their chargemasters, sometimes charging separately for overhead (for example, paper cups, gloves, transportation, staff consultations) and sometimes including charges for those supplies in the charge for drugs. Therefore, we cannot be certain that the amount of uncoded pharmacy overhead cost is as high as the public has suggested or that hospitals

mark up these uncoded drugs and biologicals in the same way as packaged drugs and biologicals with HCPCS codes.

In addition, at its February 2010 meeting, the APC Panel recommended that CMS reallocate a larger portion of the pharmacy overhead costs from packaged drugs to separately payable drugs for CY 2011. We do not accept the APC Panel's recommendation to redistribute a larger portion of the pharmacy overhead costs from packaged drugs to separately payable drugs because we also believe the analysis provided by the presenters at the February 2010 APC Panel meeting is insufficient to determine that it is appropriate to propose to redistribute more payment from uncoded packaged drugs and biologicals to separately paid drugs and biologicals. Although presenters at the APC Panel meeting acknowledged that CMS could not know the ASP for these uncoded drug costs, they provided analyses examining the proportion of estimated coded packaged drug cost relative to estimated uncoded packaged drug cost out of all packaged drug cost (both coded and uncoded) and concluded that uncoded and coded packaged drugs are probably the same drugs because hospitals tend to have roughly the same amount of estimated packaged drug cost in their claims data but wide variation on the proportion of coded packaged drugs. They also presented analyses stating that the relationship between pharmacy overhead and handling costs and the cost of drugs in the cost report data can be interpreted as providing a relationship between cost and overhead comparable to the ASP+X calculated for all drug cost in the claims data, if an aggregate ASP amount is assumed to be the same for uncoded drugs and biologicals as it is for coded packaged drugs. The presenters concluded that the uncoded packaged drug and biological cost

accounts for exactly the same drugs and biologicals as those in the coded packaged drug and biological cost and that CMS could assume the same proportional amount of overhead cost that appears in the uncoded packaged drug and biological cost as observed in the coded packaged drug cost. They asked that CMS assume that uncoded packaged drugs and biologicals resemble coded packaged drugs and biologicals and treat them comparably for purposes of estimating "overhead." We reviewed the presenters' analyses, but we believe the information they provided is insufficient in order to enable us to isolate the portion of the uncoded packaged drug and biological cost that is pharmacy overhead cost. In order to isolate the portion of uncoded packaged drug and biological cost that is pharmacy overhead cost, we believe that we would need more drug-specific information reported to us by hospitals, either through more reporting of packaged drugs on claims or through more granular cost centers on the cost report. We note that we investigated uncoded drugs further. We evaluated the services with which uncoded packaged drug cost appears in the claims data in an effort to assess how much uncoded drugs resemble coded packaged drugs. We found that most uncoded packaged drug costs appear with surgical services and that most coded packaged drug costs appear with medical services. In light of this information, we are not confident that the drugs captured by uncoded drug cost are the same drugs captured by coded packaged drug cost. Therefore, we do not believe we can assume that they are the same drugs, with comparable overhead and handling costs. Without being able to calculate an ASP for these drugs and without being able to gauge the magnitude of the overhead complexity associated with these drugs, we do not believe we should assume that the same amount of

proportional overhead is available for redistribution for this proposed rule. We are not convinced that the same proportionate amount of overhead cost should be redistributed from the packaged uncoded drugs as the amount of overhead cost that is appropriate to redistribute for packaged coded drugs. In addition, we remain committed to using hospital claims data reported to us by hospitals to set the OPPS payment rates because it provides more specificity about the provided drugs and biologicals and would allow us to assess an overhead amount for those drugs.and biologicals. Therefore, we continue to propose to redistribute a conservative estimate, $50 million, in cost from uncoded packaged drugs to separately payable drugs and biologicals

Based on the reasons set forth above, and consistent with our rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60511 through 60512), we cannot be certain that we know what portion of the uncoded drugs and biologicals cost is acquisition cost versus pharmacy overhead costs, and we have no compelling reason to redistribute a greater amount of drug cost. Therefore, our proposal to redistribute $200 million in drug cost from packaged drugs to separately payable drugs, while maintaining the total cost of drugs in our claims data, consists of redistributing $150 million in “overhead” cost from packaged coded drugs and biologicals with reported ASP data to separately payable drugs and biologicals and redistributing $50 million in drug cost from uncoded packaged drugs and biologicals to separately payable drugs and biologicals as a conservative estimate of potential overhead cost appearing in uncoded packaged drugs that should have been associated with separately payable drugs and biologicals.

We have indicated that the basis for this CY 2011 proposal to redistribute $150 million dollars from packaged coded drugs and biologicals to separately payable drugs and biologicals as a pharmacy overhead adjustment is the same as our CY 2010 final policy. The CY 2010 policy was based on our assessment that between one-third and one-half of the overhead cost in coded packaged drugs could be attributable to charge compression due to our cost estimation methodology and our choice of a packaging threshold. We continue to believe that a precise amount of drug cost attributable to charge compression cannot be known precisely, but that $150 million is an appropriate adjustment. The current proposal for $150 million falls within the approximate one-third to one-half range established in CY 2010 with updated CY 2009 claim and cost report data, and we anticipate that the $150 million would continue to roughly approximate one-third to one-half or thereabouts of overhead cost in the coded packaged drugs with updated ASP data, and claim and cost report data for the final rule. In order to redistribute the $150 million in pharmacy overhead from packaged costs of drugs and biologicals for which a HCPCS code was reported, we reduced the costs attributable to these items and services by multiplying the costs derived from the revenue center charges for packaged HCPCs codes by 0.75 (a 25 percent reduction).

To redistribute the $50 million in total cost from packaged costs of drugs and biologicals for which no HCPCS code was reported, we reduced the costs attributable to these items and services by multiplying the costs derived from revenue center charges for pharmacy by 0.92 (an 8 percent reduction). We note that for this CY 2011 OPPS/ASC proposed rule, the $50 million in drug overhead cost that we propose to redistribute from

packaged uncoded drugs and biologicals to separately payable drugs and biologicals is 8 percent, comparable to the CY 2010 final rule amount. We note that $50 million as a percent of uncoded drug cost may be close to the 8 percent range or thereabouts of uncoded drug and biological cost in the final rule with updated claim and cost data. In addition, although we have arrived at a proposed payment rate of ASP+6 percent, we emphasize that the ASP+6 percent amount may change when ASP+X is recalculated using updated ASP data and claims and cost report data for the CY 2011 OPPS/ASC final rule with comment period.

We also 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. We believe that a practice of billing all drugs and biologicals with HCPCS codes under revenue code 0636 (Pharmacy – Extension of 025X; Drugs Requiring Detailed Coding) would be consistent with NUBC billing guidelines and would provide us with the most complete and detailed information for ratesetting. We note that we make packaging determinations for drugs 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.

The APC Panel also recommended that CMS evaluate the impact of changes in its drug payment policy on hospitals (categorized by type and size) of such a reallocation

and present this analysis to the APC Panel at its next meeting. We accept this recommendation and will present this analysis to the APC Panel at its next meeting.

The APC Panel also recommended that CMS continue to evaluate the impact of its drugs and biologicals overhead payment policy on hospitals. We accept this recommendation. We note that our regulatory impact analysis presented in section XXIII. of this proposed rule includes some of the analysis requested in these last two recommendations.

In conclusion, we are proposing for CY 2011 to continue our CY 2010 redistribution methodology, to redistribute $150 million from the pharmacy overhead cost of coded packaged drugs and biologicals with an ASP and to redistribute $50 million from the cost of uncoded packaged drugs and biologicals for a total of $200 million from cost in coded and uncoded packaged drugs to separately payable drugs. We are proposing to redistribute pharmacy overhead cost among 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). The result of the proposed methodology when applied using April 2010 ASPs, data for claims for services furnished during CY 2009 and processed through the common working file before January 1, 2010, and the most current submitted cost reports as of January 1, 2010, is a proposed ASP+6 percent amount for CY 2011. We are further proposing to continue to include the claims data for 340B hospitals in the calculation of payment for drugs and biologicals under the CY 2011 OPPS because 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, and we do not believe this redistribution would be appropriate (74 FR 35332). 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 2011 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.

Finally, we note that we continue to pursue the most appropriate methodology for establishing payment for drugs and biologicals under the OPPS and that we will continue to evaluate the appropriateness of this methodology in future years.

c. Proposed Payment Policy for Therapeutic Radiopharmaceuticals

From the implementation of the collection of ASP information in CY 2005, CMS 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 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 hospital's 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 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.

We believe that the rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) continues to be appropriate in for nonpass-through separately payable therapeutic radiopharmaceuticals in CY 2011. 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 (as discussed in section V.B.3.b.)

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 2009 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.

4. Proposed Payment for Blood Clotting Factors

For CY 2010, 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 2010, we provided payment for blood clotting factors under the OPPS at ASP+4 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices under Medicare Part B and in other Medicare settings, a furnishing fee is also applied to the payment. The CY 2010 updated furnishing fee is $0.170 per unit.

For CY 2011, we are proposing to pay for blood clotting factors at ASP+6 percent, consistent with our proposed payment policy for other nonpass-through separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount. Because the 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 and 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 this proposed rule. 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 providing separate payment for therapeutic radiopharmaceuticals in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60581 through 60526), 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.

For CY 2011, we are proposing to continue the CY 2010 payment methodology for new drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals that meet the following conditions: those drugs, biologicals and therapeutic radiopharmaceuticals that have HCPCS codes that do not crosswalk to CY 2010 HCPCS codes, those that do not have pass-through status, and those that are without OPPS hospital claims data. We are proposing to provide payment for new CY 2011 drugs (excluding contrast agents and diagnostic radiopharmaceuticals), nonimplantable biologicals, and therapeutic radiopharmaceuticals , at ASP+6 percent, consistent with the proposed CY 2011 payment methodology for other separately payable nonpass-through drugs, nonimplantable biololgicals, 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 2011, generally equivalent to the payment these drug and biologicals would receive in the physician's office setting, consistent with the requirements of the statute.

We are proposing to continue our CY 2010 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 2011 diagnostic radiopharmaceutical, contrast agent, 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 2011, 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" to HCPCS codes for new drugs and nonimplantable biologicals without OPPS claims data and for which we have not granted pass-through status. We further note that, with respect to new items for which we do not have ASP data, once their ASP data become available in later quarter 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 2011 at ASP+6 percent) for items that have not been granted pass-through status. 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 2010, 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 2010 policy to base 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 a new therapeutic radiopharmaceutical at 95 percent of the product's most recent AWP because we would not have mean costs from hospital claims data upon which to base payment. Analogous to new drugs and biologicals, we 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 payments, for CY 2011, we are proposing to announce any changes to the payment amounts for new drugs and biologicals in the CY 2011 OPPS/ASC final rule with comment period and also on a quarterly basis on the CMS Web site during CY 2011 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 2011 HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals are

not available at the time of development of this proposed rule. However, they will be included in Addendum B to the CY 2011 OPPS/ASC final rule with comment period. They will be assigned comment indicator "NI" in Addendum B to reflect that their interim final OPPS treatment is open to public comment on the CY 2011 OPPS/ASC final rule with comment period.

There are several nonpass-through drugs and biologicals that were payable in CY 2009 and/or CY 2010, for which we do not have CY 2009 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. These drugs and biologicals do 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 2011, we calculated an estimate of the per day cost of each of these items by multiplying the payment rate for each product based on ASP+6 percent, similar to other nonpass-through drugs and biologicals paid separately under the OPPS, by an estimated average number of units of each product that would typically be furnished to a patient during one administration in the hospital outpatient setting. We are proposing to package items for which we estimated the per administration cost to be less than or equal to $70, which is the general packaging threshold that we are proposing for drugs, nonimplantable biologicals, and therapeutic radiopharmaceuticals in CY 2011. We are proposing to pay separately for items with an estimated per day cost greater than $70 (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 2011. We are proposing that the CY 2011 payment for separately payable items without CY 2009 claims data would be ASP+6 percent, similar to payment for other separately payable nonpass-through drugs and biologicals under the OPPS. In accordance with the ASP methodology used in the physician's office setting, in the absence of ASP data, we are proposing to use the WAC for the product to establish the initial payment rate. However, we note that if the WAC is also unavailable, we would make payment at 95 percent of the most recent AWP available.

The proposed estimated units per day and status indicators for these items are displayed in Table 27 below.

TABLE 27.—DRUGS AND BIOLOGICALS WITHOUT CY 2009 CLAIMS DATA

CY 2011 HCPCS Code	CY 2011 Long Descriptor	Estimated Average Number of Units Per Administration	Proposed CY 2011 SI	Proposed CY 2011 APC
90681	Rotavirus vaccine, human, attenuated, 2 dose schedule, live, for oral use	1	K	1239
90725	cholera vaccine for injectable use	1	K	1271
J0205	injection, alglucerase, per 10 units	420	K	0900
J0364	Injection, apomorphine hydrochloride, 1 mg	12	N	
J1835	Injection, itraconazole, 50 mg	8	K	1303
J2724	Injection, protein c concentrate, intravenous, human, 10 iu	2240	K	1139
J3355	Injection, urofollitropin, 75 IU	2	K	1741
J3485	Injection, zidovudine, 10 mg	42	N	
J7185	Injection, factor viii (antihemophilic factor, recombinant) (xyntha), per i.u.	1750	K	1268
J9215	Injection, interferon, alfa-n3, (human leukocyte derived), 250,000 iu	5	K	0865
J9226	Histrelin implant (supprelin la), 50 mg	1	K	1142
J9357	Injection, valrubicin, intravesical, 200 mg	4	K	1235
Q0515	Injection, sermorelin acetate, 1 microgram	70	K	3050

CY 2011 HCPCS Code	CY 2011 Long Descriptor	Estimated Average Number of Units Per Administration	Proposed CY 2011 SI	Proposed CY 2011 APC
Q2017	Injection ,teniposide, 50 mg	9.35	K	7035

Finally, there were five drugs and biologicals, shown in Table 28 below, that were payable in CY 2009, but for which we lacked CY 2009 claims data and any other pricing information for the ASP methodology for this 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 to status indicator "E" (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) that we understood were not currently sold or had been identified as obsolete. 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.

For CY 2011, we are proposing to continue our CY 2010 policy to assign status indicator "E" to drugs and biologicals that lack CY 2009 claims data and pricing information for the ASP methodology. All drugs and biologicals without CY 2009 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 2011 are displayed in

Table 26 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 2011.

TABLE 28.—DRUGS AND BIOLOGICALS WITHOUT CY 2009 CLAIMS DATA AND WITHOUT PRICING INFORMATION FOR THE ASP METHODOLOGY

CY 2011 HCPCS Code	CY 2011 Long Descriptor	Proposed CY 2011 SI
J0190	Injection, biperiden lactate, per 5 mg	E
J1435	Injection, estrone, per 1 mg	E
J3320	Injection, spectinomycin dihydrochloride, up to 2 gm	E
J3400	Injection, trifluprom azine hcl, up to 20 mg	E
Q0174	Thiethylperazine maleate, 10 mg, oral, fda approved prescription anti-emetic, for use as a compl	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" (defined below) of total program payments estimated to be made under section 1833(t) of the Act for all covered services furnished for that year under the hospital OPPS. For a year (or portion of a year) before CY 2004, the applicable percentage means 2.5 percent; for CY 2004 and subsequent years, the applicable percentage means 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 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 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 2011 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 would continue to be eligible for pass-through payment in CY 2011. 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 would be newly eligible, for device pass-through payment in the remaining quarters of CY 2010 or beginning in CY 2011. As discussed in section V.A.4. of the CY 2010 final rule with comment period (74 FR 60529), 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 always surgically inserted or implanted (through a surgical incision or a natural orifice) is the device pass-through process and payment methodology only. Therefore, we are proposing that the estimate of

pass-through spending for implantable biologicals newly eligible for pass-through payment beginning in CY 2011 be included in the pass-through spending estimate for this second group of device categories. The sum of the proposed CY 2011 pass-through estimates for these two groups of device categories equals the total proposed CY 2011 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 Medicare OPD fee schedule 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 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 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 would be 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 2011 OPPS at ASP+6 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 2011 pass-through drugs and nonimplantable biologicals at ASP+6 percent or the Part B drug CAP rate, if applicable, our proposed estimate of drug and nonimplantable biological pass-through payment for CY 2011 would be zero. Furthermore, payment for certain drugs, specifically diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals without pass-through status, would always be packaged into payment for the associated procedures because these products would never be separately paid. However, all pass-through diagnostic radiopharmaceuticals, contrast agents, and those implantable biologicals with pass-through status approved prior to CY 2010 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 proposed estimate of pass-through

payment for all diagnostic radiopharmaceuticals and contrast agents and those implantable biologicals with pass-through status approved prior to CY 2011 is not zero.

In section V.A.4. of this proposed rule, we discuss our policy to determine if the cost of certain "policy-packaged" drugs, including diagnostic radiopharmaceuticals and contrast agents, are already packaged into the existing APC structure. If we determine that a "policy-packaged" drug approved for pass-through payment resembles predecessor diagnostic radiopharmaceuticals or contrast agents already included in the costs of the APCs that 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 have not established a policy to offset pass-through payment for implantable biologicals when approved for pass-through payment as a drug or biological, that is, for CY 2009 and earlier, so we would consider full payment at ASP+6 percent for these implantable biologicals receiving biological pass-through payment as of CY 2011 in our proposed estimate of CY 2011 pass-through spending for drugs and biologicals.

We note that the Part B drug CAP program has been suspended beginning January 1, 2009. We refer readers to the Medicare Learning Network (MLN) Matters Special Edition article SE0833 for more information on this suspension. As of the publication of this proposed rule, the Part B drug CAP program has not been reinstituted. Therefore, for this proposed rule, we are proposing to continue to 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 biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that would continue to be eligible for pass-through payment in CY 2011. The second group contains drugs and nonimplantable biologicals that we know are newly eligible, or project would be newly eligible, in the remaining quarters of CY 2010 or beginning in CY 2011. The sum of the CY 2011 pass-through estimates for these two groups of drugs and biologicals would equal the total CY 2010 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 2011, consistent with our OPPS policy from CY 2004 through CY 2010 (74 FR 60530).

For the first group of devices for pass-through payment estimate purposes, there currently are no device categories receiving pass-through payment in CY 2010 that would continue for payment during CY 2011. Therefore, we are proposing a device

pass-through payment estimate for the first group of pass-through device categories of $0.

We also are proposing for CY 2011 to continue to employ the device pass-through process and payment methodology for implantable biologicals that are always surgically inserted or implanted (through a surgical incision or a natural orifice) that we used for CY 2010. We are proposing to consider existing implantable biologicals approved for pass-through payment under the drugs and biologicals pass-through provision prior to CY 2010 as drugs and biologicals for pass-through payment estimate purposes until they expire from pass-through status. Therefore, the proposed pass-through spending estimate for the first group of pass-through devices does not include implantable biologicals that were granted pass-through status prior to CY 2010. Finally, we are proposing to continue to provide payment for implantable biologicals newly eligible for pass-through payment beginning in CY 2010 or CY 2011 based on hospital charges adjusted to cost that is applicable for pass-through device categories, rather than the ASP methodology that is applicable to pass-through drugs and biologicals. Therefore, we are proposing that the estimate of pass-through spending for implantable biologicals first paid as pass-through devices in CY 2011 would be based on the payment methodology for pass-through devices and would be included in the device pass-through spending estimate.

In estimating our proposed CY 2011 pass-through spending for device categories in the second group, that is, device categories that we knew at the time of the development of the proposed rule would be newly eligible for pass-through payment in

CY 2011 (of which there are none), additional device categories (including categories that describe implantable biologicals) that we estimated could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2011, and contingent projections for new categories (including categories that describe implantable biologicals in the second through fourth quarters of CY 2011), 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. While there are no new device categories (including categories that describe implantable biologicals) for CY 2011 of which we are aware at the time of development of this proposed rule, there are possible new device categories for pass-through payment based on current applications. Therefore, the estimate of CY 2011 pass-through spending for this second group of device categories is $72.1 million.

Employing our established methodology that the estimate of pass-through device spending in CY 2011 incorporates CY 2011 estimates of pass-through spending for known device categories continuing in CY 2011, those known or projected to be first effective January 1, 2011, and those device categories projected to be approved during subsequent quarters of CY 2010 or CY 2011, our proposed CY 2011 estimate of total pass-through spending for device categories is $72.1 million.

To estimate CY 2011 proposed pass-through spending for drugs and biologicals in the first group, specifically those drugs (including radiopharmaceuticals and contrast agents) and biologicals (including implantable biologicals) recently made eligible for

pass-through payment and continuing on pass-through status for CY 2011, we are proposing to utilize the most recent Medicare physician's office data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals, in order to project the CY 2011 OPPS utilization of the products.

For the known drugs and biologicals (excluding diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals) that would be continuing on pass-through status in CY 2011, we then estimate the proposed pass-through payment amount as the difference between ASP+6 percent or the Part B drug CAP rate, as applicable, and ASP+6 percent, aggregated across the projected CY 2011 OPPS utilization of these products, which is zero for this group of drugs and biologicals. 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 include in the pass-through estimate the difference between payment for the drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP information is not available) and the "policy-packaged" drug APC offset amount, if we determined that the diagnostic radiopharmaceutical or contrast agent approved for pass-through payment resembles predecessor diagnostic radiopharmaceuticals or contrast agents already included in the costs of the APCs that would be associated with the drug receiving pass-through payment. Because payment for an implantable biological eligible for pass-through payment in CY 2009 and continuing on pass-through status in CY 2011 would be

packaged if the product were not paid separately due to its pass-through status and because we had not established a pass-through payment offset policy for implantable biologicals when approved for pass-through payment as biologicals, that is, for CY 2009 and earlier, we are including in the proposed pass-through spending estimate the full payment for these implantable biologicals at ASP+6 percent (or WAC+6 percent or 95 percent of AWP, if ASP information is not available). Based on these results, we are proposing the spending estimate for this first group of drugs and biologicals to be $9 million, while we are proposing our spending estimate for the second group of drugs and biologicals to be $5.8 million.

To estimate CY 2011 pass-through spending for drugs and nonimplantable biologicals in the second group (that is, drugs and nonimplantable biologicals that we knew at the time of development of this proposed rule would be newly eligible for pass-through payment in CY 2011, additional drugs and nonimplantable biologicals that we estimated could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2011, 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 2011), 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 2011 proposed pass-through payment estimate. We also are considering the most recent OPPS experience in approving new pass-through drugs and nonimplantable biologicals. Consistent with our

policy established in CY 2010 (74 FR 60531 through 60532), we also are proposing to include new implantable biologicals that we expect to be approved for pass-through status as devices beginning in CY 2011 in the second group of items considered for device pass-through estimate purposes. Therefore, we are not proposing to include implantable biologicals in the second group of items in the proposed drug and biological pass-through spending estimate.

Based on the results of these analyses, we are proposing that the spending estimate for this second group of drugs and biologicals to be $5.8 million.

As described in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60476), under our current policy, beginning in CY 2010, implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) and that were not receiving pass-through payment as biologicals prior to January 1, 2010, will be evaluated under the device pass-through process and paid according to the device payment methodology. We are proposing to continue to consider implantable biologicals approved for pass-through payment under the drug and biological pass-through provision prior to CY 2010 as drugs and biologicals for pass-through payment estimate purposes. These implantable biologicals that have been approved for pass-through status prior to CY 2010 continue to be considered drugs and biologicals until they expire from pass-through status. Therefore, the pass-through spending estimate for the first group of pass-through device categories does not include implantable biologicals that have been granted pass-through status prior to CY 2010.

Consistent with the current policy established in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60476), we are proposing to continue to provide that payment for implantable biologicals newly eligible for pass-through payment beginning in CY 2011 is based on hospital charges adjusted to cost, rather than the ASP methodology that is applicable to pass-through drugs and biologicals. Therefore, we are proposing that the estimate of pass-through spending for implantable biologicals first paid as pass-through devices in CY 2011 would be based on the payment methodology for pass-through devices, and would be included in the proposed CY 2011 device pass-through spending estimate for the second group of pass-through device categories.

The proposed CY 2011 pass-through spending estimate for the first group of pass-through device categories is $0. The proposed estimate of CY 2010 pass-through spending for the second group of pass-through device categories is $72.1 million. Our proposed CY 2011 estimate of total pass-through spending for device categories is $72.1 million.

The estimate for pass-through spending for the first group of drugs and biologicals is $9.0 million for CY 2011. The estimate for pass-through spending for the second group of drugs and biologicals is $5.8 million for CY 2011. As discussed in section V.A. of this proposed rule, radiopharmaceuticals are considered drugs for pass-through purposes. Therefore, we have included radiopharmaceuticals in our proposed CY 2011 pass-through spending estimate for drugs and biologicals. Our proposed CY 2011 estimate of total pass-through spending for drugs and biologicals is $14.8 million.

In summary, in accordance with the methodology described above in this section, we estimate that total pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2011 and those device categories, drugs, and nonimplantable biologicals that first become eligible for pass-through payment during CY 2011 would be approximately $86.9 million, which represents 0.20 percent of total OPPS projected total payments for CY 2011. We estimate that pass-through spending in CY 2011 would not amount to 2.0 percent of total projected OPPS CY 2011 program spending.

VII. Proposed OPPS Payment for 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.

In our CY 2007 annual OPPS rulemaking, we proposed and finalized a policy of prospective payment based on median costs for the 11 brachytherapy sources for which we had claims data. We based the prospective payment rates on median costs for each source from our CY 2005 claims data (71 FR 68102 through 71 FR 68115).

Subsequent to publication of the CY 2007 OPPS/ASC final rule with comment period, section 107 of Pub. L. 109-432 (MIEA-TRHCA) amended section 1833 of the Act. Specifically, section 107(a) of Pub. L. 109-432 amended section 1833(t)(16)(C) of the Act by extending the payment period for brachytherapy sources based on a hospital's charges adjusted to cost for one additional year, through December 31, 2007. Therefore, we continued to pay for brachytherapy sources based on charges adjusted to cost for CY 2007.

Section 107(b)(1) of Pub. L. 109-432 amended section 1833(t)(2)(H) of the Act by adding a requirement for the establishment of separate payment groups for "stranded and non-stranded" brachytherapy sources furnished on or after July 1, 2007, in addition to the existing requirements for separate payment groups based on the number, isotope, and radioactive intensity of brachytherapy sources under section 1833(t)(2)(H) of the Act. Section 107(b)(2) of Pub. L. 109-432 authorized the Secretary to implement this requirement by "program instruction or otherwise." We note that public commenters

who responded to the CY 2007 OPPS/ASC proposed rule asserted that stranded sources, which they described as embedded into the stranded suture material and separated within the strand by material of an absorbable nature at specified intervals, had greater production costs than non-stranded sources (71 FR 68113 through 68114).

As a result of the statutory requirement to create separate groups for stranded and non-stranded sources as of July 1, 2007, we established several coding changes through a transmittal, effective July 1, 2007 (Transmittal 1259, dated June 1, 2007). Based on public comments received on the CY 2007 OPPS/ASC proposed rule and industry input, we were aware of three sources available in stranded and non-stranded forms at that time: iodine-125; palladium-103; and cesium-131 (72 FR 42746). We created six new HCPCS codes to differentiate the stranded and non-stranded versions of iodine, palladium, and cesium sources.

In Transmittal 1259, we indicated that if we receive information that any of the other sources now designated as non-stranded are also FDA-approved and marketed as a stranded source, we would create a code for the stranded source. We also established two "Not Otherwise Specified" (NOS) codes for billing stranded and non-stranded sources that are not yet known to us and for which we do not have source-specific codes. We established HCPCS code C2698 (Brachytherapy source, stranded, not otherwise specified, per source) for stranded NOS sources and HCPCS code C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source) for non-stranded NOS sources.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66784), we again finalized prospective payment for brachytherapy sources, beginning in CY 2008,

with payment rates determined using the CY 2006 claims-based costs per source for each brachytherapy source. Consistent with our policy regarding APC payments made on a prospective basis, we finalized the policy in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66686) to subject the cost of brachytherapy sources to the outlier provision of section 1833(t)(5) of the Act, and also to subject brachytherapy source payment weights to scaling for purposes of budget neutrality. Therefore, brachytherapy sources could receive outlier payments if the costs of furnishing brachytherapy sources met the criteria for outlier payment, that is, if brachytherapy sources are paid prospectively. In addition, as noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66683), implementation of prospective payment for brachytherapy sources would provide opportunities for hospitals to receive additional payments under certain circumstances through the 7.1 percent rural SCH adjustment (discussed in section II.E. of this proposed rule).

For CY 2008, we also proposed and finalized a policy regarding payment for new brachytherapy sources for which we have no claims data (72 FR 42749 and 72 FR 66786, respectively). We indicated we would 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. Finally, we proposed and finalized our policy to discontinue using status indicator "H" (Pass-Through Device Categories. Separate cost based pass-through payment; not subject to copayment) because we would not be paying charges adjusted to costs after December 31, 2007, and instead adopted a policy

of using status indicator “K” (which includes, among others, “Brachytherapy Sources. Paid under OPPS; separate APC payment”) for CY 2008 (72 FR 42749 and 72 FR 66785, respectively).

After we finalized these policies for CY 2008, section 106(a) of Pub. L. 110-173 (MMSEA) extended the charges-adjusted-to-cost payment methodology for brachytherapy sources for an additional 6 months, through June 30, 2008. Because our final CY 2008 policies paid for brachytherapy sources at prospective rates based on median costs, we were unable to implement these policies during this extension.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41502), we again proposed prospective payment rates for brachytherapy sources for CY 2009. We proposed to pay for brachytherapy sources at prospective rates based on their source-specific median costs as calculated from CY 2007 claims data available for CY 2009 ratesetting. Subsequent to issuance of the CY 2009 OPPS/ASC proposed rule, Pub. L. 110-275 (MIPPA) was enacted on July 15, 2008. Section 142 of Pub. L. 110-275 amended section 1833(t)(16)(C) of the Act, as amended by section 106(a) of Pub. L. 110-173 (MMSEA), to further extend the payment period for brachytherapy sources based on a hospital's charges adjusted to cost from July 1, 2008 through December 31, 2009. Therefore, we continued to pay for brachytherapy sources at charges adjusted to cost in CY 2008 from July 1 through December 31, and we maintained the assignment of status indicator “H” to brachytherapy sources for claims processing purposes in CY 2008. For CY 2009, we continued to pay for all separately payable brachytherapy sources based on a hospital's charges adjusted to cost. Because brachytherapy sources are paid at charges adjusted to

cost, we did not subject them to outlier payments under section 1833(t)(5) of the Act, or subject brachytherapy source payment weights to scaling for purposes of budget neutrality. Moreover, during the CY 2009 period of payment at charges adjusted to cost, brachytherapy sources were not eligible for the 7.1 percent rural SCH adjustment (as discussed in detail in section II.E. of this proposed rule).

Furthermore, for CY 2009, we did not adopt the policy we established in the CY 2008 OPPS/ASC final rule with comment period of paying stranded and non-stranded NOS codes for brachytherapy sources, HCPCS codes C2698 and C2699, based on a rate equal to the lowest stranded or non-stranded prospective payment for such sources. Also, for CY 2009, we did not adopt the policy we established in the CY 2008 OPPS/ASC final rule with comment period regarding payment for new brachytherapy sources for which we have no claims data. NOS HCPCS codes C2698 and C2699 and newly established specific source codes were paid at charges adjusted to cost through December 31, 2009, consistent with the provisions of section 142 of Pub. L. 110-275.

For CY 2009, we finalized our proposal to create new status indicator "U" (Brachytherapy Sources. Paid under OPPS; separate APC payment) for brachytherapy source payment, instead of using status indicator "K" as proposed and finalized for CY 2008 for prospective payment, or status indicator "H," used during the period of charges adjusted to cost payment. As noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68670), assigning a status indicator, such as status indicator "K," to several types of items and services with potentially differing payment policies added unnecessary complexity to our operations. Status indicator "U" is used only for

brachytherapy sources, regardless of their specific payment methodology for any period of time.

Under section 142 of Pub. L. 110-275, payment for brachytherapy sources was mandated at charges adjusted to cost only through CY 2009. 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.

B. Proposed OPPS Payment Policy

As we have previously stated (72 FR 66780, 73 FR 41502, and 74 FR 60533 and 60534), 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 the OPPS prospective payment methodology 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.

We are proposing to use the median costs from CY 2009 claims data for setting the proposed CY 2011 payment rates for brachytherapy sources, as we are proposing for

most other items and services that will be paid under the CY 2011 OPPS. We are proposing to continue the other payment policies for brachytherapy sources we finalized 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 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 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, as we did for CY 2010, 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. Therefore, brachytherapy sources could receive outlier payments if the costs of furnishing brachytherapy sources meet the criteria for outlier payment, that is, if they are prospectively paid. In addition, as noted in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60534), implementation of prospective payments for brachytherapy sources would provide opportunities for hospitals to receive additional payments in CY 2010 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 2011. The separately payable brachytherapy source HCPCS codes, long descriptors, APCs, status indicators, and approximate APC median costs that we are proposing for CY 2011 are presented in Table 29 below.

TABLE 29.—PROPOSED SEPARATELY PAYABLE BRACHYTHERAPY SOURCES FOR CY 2011

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 APC	Proposed CY 2011 SI	Proposed CY 2011 Approximate APC Median Cost
A9527	Iodine I-125, sodium iodide solution, therapeutic, per millicurie	2632	U	$21
C1716	Brachytherapy source, non-stranded, Gold-198, per source	1716	U	$188
C1717	Brachytherapy source, non-stranded, High Dose Rate Iridium-192, per source	1717	U	$225
C1719	Brachytherapy source, non-stranded, Non-High Dose Rate Iridium-192, per source	1719	U	$23

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 APC	Proposed CY 2011 SI	Proposed CY 2011 Approximate APC Median Cost
C2616	Brachytherapy source, non-stranded, Yttrium-90, per source	2616	U	$17,108
C2634	Brachytherapy source, non-stranded, High Activity, Iodine-125, greater than 1.01 mCi (NIST), per source	2634	U	$53
C2635	Brachytherapy source, non-stranded, High Activity, Palladium-103, greater than 2.2 mCi (NIST), per source	2635	U	$30
C2636	Brachytherapy linear source, non-stranded, Palladium-103, per 1MM	2636	U	$37
C2638	Brachytherapy source, stranded, Iodine-125, per source	2638	U	$39
C2639	Brachytherapy source, non-stranded, Iodine-125, per source	2639	U	$37
C2640	Brachytherapy source, stranded, Palladium-103, per source	2640	U	$65
C2641	Brachytherapy source, non-stranded, Palladium-103, per source	2641	U	$64
C2642	Brachytherapy source, stranded, Cesium-131, per source	2642	U	$117
C2643	Brachytherapy source, non-stranded, Cesium-131, per source	2643	U	$64
C2698	Brachytherapy source, stranded, not otherwise specified, per source	2698	U	*$39
C2699	Brachytherapy source, non-stranded, not otherwise specified, per source	2699	U	*$23

*Median cost is that of the lowest cost stranded or non-stranded source upon which proposed CY 2011 payment for the NOS HCPCS code is based.

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.

VIII. Proposed OPPS Payment for Drug Administration Services

A. Background

In CY 2005, in response to the recommendations made by public commenters and the hospital industry, OPPS transitioned from Level II HCPCS Q-codes to the use of CPT codes for drug administration services. These CPT codes allowed specific reporting of services regarding the number of hours for an infusion and provided consistency in coding between Medicare and other payers. (For a discussion regarding coding and payment for drug administration services prior to CY 2005, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66787).)

While hospitals began adopting CPT codes for outpatient drug administration services in CY 2005, physicians paid under the MPFS were using HCPCS G-codes in CY 2005 to report office-based drug administration services. These HCPCS G-codes were developed in anticipation of substantial revisions to the drug administration CPT codes by the CPT Editorial Panel that were expected for CY 2006.

In CY 2006, as anticipated, the CPT Editorial Panel revised its coding structure for drug administration services and incorporated new concepts, such as initial, sequential, and concurrent services, into a structure that previously distinguished services based on type of administration (chemotherapy/nonchemotherapy), method of administration (injection/infusion/push), and for infusion services, first hour and additional hours. For

CY 2006, we implemented the CY 2006 drug administration CPT codes that did not reflect the concepts of initial, sequential, and concurrent services under the OPPS, and we created HCPCS C-codes that generally paralleled the CY 2005 CPT codes for reporting these other services.

For CY 2007, as a result of public comments on the proposed rule and feedback from the hospital community and the APC Panel, we implemented the full set of CPT codes for drug administration services, including codes incorporating the concepts of initial, sequential, and concurrent services. In addition, the CY 2007 update process offered us the first opportunity to consider data gathered from the use of CY 2005 CPT codes for purposes of ratesetting. For CY 2007, we used CY 2005 claims data to implement a six-level APC structure for drug administration services. In CY 2008, we continued to use the full set of CPT codes for drug administration services and continued our assignment of drug administration services to this six-level APC structure.

For CY 2009, we continued to allow hospitals to use the full set of CPT codes for drug administration services but moved from a six-level APC structure to a five-level APC structure. We note that, while there were changes in the CPT numerical coding for nonchemotherapy drug administration services in CY 2009, the existing CPT codes were only renumbered, and there were no significant changes to the code descriptors themselves. As we discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68672), the CY 2009 ratesetting process afforded us the first opportunity to examine hospital claims data for the full set of CPT codes that reflected the concepts of initial, sequential, and concurrent services. For CY 2009, we performed our standard

annual OPPS review of the clinical and resource characteristics of the drug administration CPT codes assigned to the six-level CY 2008 APC structure based on the CY 2007 claims data available for the CY 2009 OPPS/ASC proposed rule. As a result of our hospital cost analysis and detailed clinical review, we adopted a five-level APC structure for CY 2009 drug administration services to more appropriately reflect their resource utilization in APCs that also group clinically similar services. As we noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68671), these APCs generally demonstrated the clinically expected and actually observed comparative relationships between the median costs of different types of drug administration services, including initial and additional services; chemotherapy and other diagnostic, prophylactic, or therapeutic services; injections and infusions; and simple and complex methods of drug administration.

After analyzing the assignment of CPT codes for drug administration into the five-level APC structure by utilizing our standard annual OPPS review for clinical cohesiveness and resource homogeneity, we continued our five-level APC structure for payment for drug administration services in the HOPD for CY 2010. In addition, we used the full set of CPT codes for drug administration and included all separately payable drug administration add-on codes on the CY 2010 bypass list in order to create pseudo single claims for these codes that would enable us to use the claims data to set payment rates for them. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60538) since CY 2007, we continue to update the bypass methodology to reflect changing drug administration HCPCS codes that are recognized under the OPPS.

B. Proposed Coding and Payment for Drug Administration Services

For CY 2011, we are proposing to continue to use the full set of CPT codes for reporting drug administration services and to continue to pay separately for the same set of drug administration codes under the CY 2011 OPPS as were paid separate in the CY 2010 OPPS. As a part of our standard annual review, we analyzed the CY 2009 claims data that reflect assignments of CPT codes for drug administration into the five-level APC structure and have found that the assignment of separately paid drug administration codes to five APCs continues to appropriately reflect the relative resources required to furnish these services. In addition, as has been our standard policy since the CY 2007 OPPS (71 FR 68117), we are proposing to continue to include all separately payable drug administration add-on codes on the bypass list so that we can use the cost data we derive from claims for these codes to establish payment rates for them.

Since this approach was first adopted for CY 2007, we have updated and expanded the bypass methodology to reflect changing drug administration HCPCS codes that are recognized under the OPPS. We placed all of the add-on CPT codes for drug administration services, including the sequential infusion and intravenous push codes, on the bypass list in CY 2009 (73 FR 68513) in order to continue this framework for transforming these otherwise unusable multiple bills into "pseudo" single claims that can be used for OPPS ratesetting purposes. We believe that this longstanding methodology results in appropriate payment rates for the add-on CPT codes for drug administration; therefore, we are proposing to continue to use this methodology for the CY 2011 OPPS because we believe this methodology takes into account all of the packaging on claims

for drug administration services and therefore provides a reasonable framework for developing median costs for drug administration services that are often provided in combination with one another (74 FR 60539).

At its February 2010 meeting, the APC Panel recommended that CMS make CPT code 96368 (Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure) and CPT code 93676 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary, separately payable procedure) separately payable for the CY 2011 OPPS at an appropriate payment rate as determined by CMS. We are not proposing to accept this APC Panel recommendation because these two codes each describe services that, by definition, are always provided in conjunction with an initial drug administration code and therefore are appropriately packaged into the payment for the separately payable services that they usually accompany. These services have been packaged since the inception of the OPPS, and we continue to believe they are appropriately packaged into the payment for the separately payable services without which, under CPT guidelines and definitions, they cannot be appropriately reported. We refer readers to section II.A.3. of this proposed rule for a more detailed discussion of payment for packaged services.

Table 30 below displays the proposed configuration of the five drug administration APCs for CY 2011 and the proposed median cost for each of the proposed drug administration APCs. We believe the updated CY 2009 claims data and the most

recent cost report data for the drug administration CPT show that these codes share sufficiently similar clinical and resource characteristics to justify their continued placement in the five levels of drug administration APCs that were in effect in the CY 2010 OPPS. The median cost for each of the separately paid drug administration CPT codes is contained in the CPT median cost file that is provided as supporting documentation to this proposed rule at the Web site at: http://www.cms.hhs.gov/HospitalOutpatientPPS/. The proposed CY 2011 payment rate for each of the proposed drug administration APCs is contained in Addendum B of this proposed rule.

TABLE 30.—PROPOSED CY 2011 DRUG ADMINISTRATION APCs

CY 2011 HCPCS Code	Proposed CY 2011 APC	Proposed CY 2011 Approximate APC Median Cost	CY 2010 Long Descriptor
90471	0436	$27	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular \injections); one vaccine (single or combination vaccine/toxoid)
90472			Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)
90473			Immunization administration by intranasal or oral route; one vaccine (single or combination vaccine/toxoid)
90474			Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)
95115			Professional services for allergen immunotherapy not including provision of allergenic extracts; single injection

CY 2011 HCPCS Code	Proposed CY 2011 APC	Proposed CY 2011 Approximate APC Median Cost	CY 2010 Long Descriptor
95117			Professional services for allergen immunotherapy not including provision of allergenic extracts; 2 or more injections
95165			Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)
96361			Intravenous infusion, hydration; each additional hour (List separately in addition to code for primary procedure)
96366			Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
96371			Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)
96372			Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96379			Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion
96549			Unlisted chemotherapy procedure
95144	0437	$38	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single dose vial(s) (specify number of vials)
95145			Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); single stinging insect venom
95148			Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 4 single stinging insect venoms
95149			Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 5 single stinging insect venoms
95170			Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; whole body extract of biting insect or other arthropod (specify number of doses)

CY 2011 HCPCS Code	Proposed CY 2011 APC	Proposed CY 2011 Approximate APC Median Cost	CY 2010 Long Descriptor
96367			Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion, up to 1 hour (List separately in addition to code for primary procedure)
96370			Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
96373			Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intra-arterial
96374			Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
96375			Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in additional to code for primary procedure)
96401			Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic
96402			Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic
96405			Chemotherapy administration; intralesional, up to and including 7 lesions
96415			Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
95146	0438	$78	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 2 single stinging insect venoms
95147			Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 3 single stinging insect venoms
96360			Intravenous infusion, hydration; initial, 31 minutes to 1 hour
96411			Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure)
96417			Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)

CY 2011 HCPCS Code	Proposed CY 2011 APC	Proposed CY 2011 Approximate APC Median Cost	CY 2010 Long Descriptor
96420			Chemotherapy administration, intra-arterial; push technique
96423			Chemotherapy administration, intra-arterial; infusion technique, each additional hour (List separately in addition to code for primary procedure)
96542			Chemotherapy injection, subarachnoid or intraventricular via subcutaneous reservoir, single or multiple agents
95990	0439	$129	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular);
95991			Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular); administered by physician
96365			Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96369			Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)
96406			Chemotherapy administration; intralesional, more than 7 lesions
96409			Chemotherapy administration; intravenous, push technique, single or initial substance/drug
96440			Chemotherapy administration into pleural cavity, requiring and including thoracentesis
96521			Refilling and maintenance of portable pump
96522			Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (eg, intravenous, intra-arterial)
96413	0440	$208	Chemotherapy administration; intravenous infusion technique; up to 1 hour, single or initial substance/drug
96416			Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
96422			Chemotherapy administration, intra-arterial; infusion technique, up to 1 hour

CY 2011 HCPCS Code	Proposed CY 2011 APC	Proposed CY 2011 Approximate APC Median Cost	CY 2010 Long Descriptor
96425			Chemotherapy administration, intra-arterial; infusion technique, initiation of prolonged infusion (more than 8 hours), requiring the use of a portable or implantable pump
96445			Chemotherapy administration into peritoneal cavity, requiring and including peritoneocentesis
96450			Chemotherapy administration, into CNS (eg, intrathecal), requiring and including spinal puncture
C8957			Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than eight hours), requiring use of portable or implantable pump

IX. 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 2011. These codes are listed below in Table 31.

TABLE 31.—PROPOSED HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES

CY 2010 HCPCS Code	CY 2010 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 2010 APC Panel meeting, the APC Panel recommended that CMS continue to report on clinic and emergency department visits and observation services in the claims data, and that 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 adopting these recommendations and plan to provide the requested data and analyses to the APC Panel at an upcoming meeting.

B. Proposed Policies for Hospital Outpatient Visits

1. Clinic Visits: New and Established Patient Visits

As reflected in Table 31, 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. For CY 2011, we are proposing to continue recognizing 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 this proposed rule and consistent with our CY 2010 policy, when calculating the median costs for the clinic visit APCs (0604 through 0608), we would 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 2011.

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 created 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.

Based on the CY 2009 claims data available for this proposed rule, we note that 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, as demonstrated in Table 32 below. Therefore, we are proposing 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. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60550), we continue to believe that this configuration pays appropriately for each level of Type B emergency department visits based on estimated resource costs from more recent claims data. We also note that, as discussed in section II.A.2.e.(1) of

this proposed rule and consistent with our CY 2010 policy, when calculating the 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 will result in the most accurate cost estimates for APCs 0604 through 0608 for CY 2011.

Table 32 below displays the proposed median costs for each level of Type B emergency department visit APCs under the proposed CY 2011 configuration, compared to the proposed median costs for each level of clinic visit APCs and each level of Type A emergency department visit APCs.

TABLE 32.—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 2011 Clinic Visit Approximate APC Median Cost	Proposed CY 2011 Type B Emergency Department Approximate APC Median Cost	Proposed CY 2011 Type A Emergency Visit Approximate APC Median Cost
Level 1	$52	$44	$54
Level 2	$74	$65	$92
Level 3	$95	$104	$146
Level 4	$125	$169	$234
Level 5	$172	$270	$347

During the February 2010 APC Panel meeting, the APC Panel requested that CMS provide information about the common diagnoses and services furnished with critical care services. We are accepting the APC Panel's recommendation and will provide the requested information at an upcoming meeting of the APC Panel.

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. Since publication of the CY 2008 OPPS/ASC final rule with comment period, we have again examined the distribution of clinic and Type A emergency department visit levels based upon updated CY 2009 claims data

available for this CY 2011 proposed rule and confirmed that we continue to observe a normal and stable distribution of clinic and emergency department visit levels in hospital claims. We continue to believe that, based on the use of their own internal guidelines, hospitals are generally billing in an appropriate and consistent manner that distinguishes among different levels of visits based on their required hospital resources. As a result of our updated analyses, we are encouraging hospitals to continue to report visits during CY 2011 according to their own internal hospital guidelines. In the absence of national guidelines, we will continue to regularly reevaluate patterns of hospital outpatient visit reporting at varying levels of disaggregation below the national level to ensure that hospitals continue to bill appropriately and differentially for these services. 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.

We appreciate all of the comments we have received in the past from the public on visit guidelines, and we encourage continued submission of comments throughout the year that would assist us and other stakeholders interested in the development of national

guidelines. Until national guidelines are established, hospitals should continue using their own internal guidelines to determine the appropriate reporting of different levels of clinic and emergency department visits. While we understand the interest of some hospitals in having us move quickly to promulgate national guidelines that would ensure standardized reporting of hospital outpatient visit levels, we believe that the issues and concerns identified both by us and others are important and require serious consideration prior to the implementation of national guidelines.

Because of our commitment to provide hospitals with 6 to 12 months notice prior to implementation of national guidelines, we would not implement national guidelines prior to CY 2012. Our goal is to ensure that OPPS national or hospital-specific visit guidelines continue to facilitate consistent and accurate reporting of hospital outpatient visits in a manner that is resource-based and supportive of appropriate OPPS payments for the efficient and effective provision of services to beneficiaries during visits in hospital outpatient settings.

X. 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 the 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.

Section 1301(a) of the recently enacted Health Care and Education Reconciliation Act of 2010 (HCERA 2010) (Pub. L. 111-152, enacted on March 30, 2010) revised the definition of a CMHC set forth at section 1861(ff)(3)(B) of the Act by adding a provision that the CMHC, effective on the first day of the first calendar quarter that begins at least 12 months after the date of enactment (that is, April 1, 2011), must provide at least 40 percent of its services to individuals who are not eligible for benefits under Title XVIII of the Act (Medicare). Section 1301(b) of HCERA 2010 amended the description of a PHP to specify that the program must be a distinct and organized intensive ambulatory treatment service offering less than 24-hour daily care "other than in an individual's home or in an inpatient or residential setting." We discuss our proposal to incorporate these two provisions of HCERA 2010 in our regulations under section X.C. of this proposed rule.

Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the HOPD services to be covered under the OPPS. The existing Medicare regulations at 42 CFR 419.21 that implement this provision specify 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 requires the Secretary to establish relative payment weights for covered HOPD services (and any APCs) based on median (or mean, at the election of the Secretary) hospital costs using data on claims from 1996 and data from the most recent available

cost reports. 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).

From CY 2003 through CY 2006, the median per diem cost for CMHCs fluctuated significantly from year to year (from a high of $685 in CY 2003 to a low of $154 in CY 2006), while the median per diem cost for hospital-based PHPs remained relatively constant ($177-$225). We believe that CMHCs may have increased and decreased their charges in response to Medicare payment policies.

Due to these significant fluctuations and declines in CMHC PHP median per diem costs, in developing the CY 2008 update, we began an effort to strengthen the PHP benefit through extensive data analysis and policy and payment changes (72 FR 66670 through 66676). Specifically, we proposed and finalized two refinements to the methodology for computing the PHP median. First, we remapped 10 revenue codes that are common among hospital-based PHP claims to the most appropriate cost centers. Secondly, we refined our methodology for calculating PHP per diem costs by computing the median using a per day methodology. A complete discussion of these refinements can be found in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66671 through 66672).

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. As noted in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68694), we believe that 3 services should be the minimum number of services allowed in a PHP day because a day with 1 or 2 services does not meet the statutory intent of a PHP. Three services are a minimum threshold that will take into consideration unforeseen circumstances, such as medical appointments, while maintaining the integrity of the PHP benefit.

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 68694 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 are reflected for the first time in the claims data that we are using to determine proposed payment rates for this CY 2011 rulemaking.

B. Proposed PHP APC Update for CY 2011

For CY 2011, we used CY 2009 claims data and computed median per diem costs in the following three categories: (1) all days; (2) days with 3 services; and (3) days with 4 or more services. These proposed median per diem costs were computed separately for CMHC PHPs and hospital-based PHPs and are shown in Table 33 below.

TABLE 33.—PHP MEDIAN PER DIEM COSTS FOR CMHC AND HOSPITAL-BASED PHPs, BY CATEGORY, BASED ON CY 2009 CLAIMS DATA

Category	CMHC PHPs	Hospital-Based PHPs	Combined
All Days	$123.17	$235.58	$132.28
Days with 3 services	$118.19	$184.47	$140.96
Days with 4 or more services	$123.35	$235.58	$131.56

Using CY 2009 data and the refined methodology for computing PHP per diem costs that we adopted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66672), we computed a median per diem cost from all claims for CY 2011 of $132.28. The data indicate that, although CMHCs provided more days with 4 or more services in CY 2009 than in CY 2008, their median per diem cost for 4 or more services ($123.35) is substantially lower than the median per diem cost for the same units of service provided in hospital-based PHPs ($235.58). The median per diem cost for claims containing 4 or more services for all PHP claims, regardless of site of service, is $131.56. Medians for claims containing 3 services is $118.19 for CMHC PHPs, $184.47 for hospital-based PHPs, and $140.96 for all PHP service claims, regardless of site of service.

These data, along with data from previous years, show the shift in cost and utilization for CMHCs and hospital-based PHPs under the two-tiered payment system. Since CY 2009 (using 2007 data), CMHC costs decreased from $139 in CY 2009 to $118 in CY 2011 for Level I services (3 services) and from $172 in CY 2009 to $123 in CY 2011 for Level II services (4 or more services). For hospital-based PHPs, costs increased

from $157 in CY 2009 to $184 in CY 2011 for Level I services (3services) and from $200 in CY 2009 to $236 in CY 2011 for Level II services (4 or more services). For the past two years, we have based the PHP APC per diem payment rates on only hospital-based PHP data because including the CMHC data would have lowered the PHP APC per diem rates and raised concerns about appropriate payment for PHP services. Specifically, we were concerned about paying hospital-based PHP programs a rate that is lower than what their cost structure reflects, which in turn could lead to hospital-based program closures and possible access problems. We also were concerned about further reducing the payment rates without knowing the impact of the policy and payment changes we made in CY 2009.

Because the CMHC cost data has significantly decreased again this year, we believe that we can no longer ignore the pattern and continue to base the PHP payment rates using only hospital-based data. We are confident that the CY 2009 claims data reflect that CMHCs continue to have a lower cost structure than hospitals and not the impact of CY 2009 policies. Therefore, we believe that we cannot continue to treat these two provider types the same in terms of payment, particularly because their cost differences continue to be so disparate. We also believe that we need to continue to protect hospital-based PHPs from receiving inadequate payments, given that they offer the widest access to PHP services because they are located across the country. We believe that the results of our analysis of the claims data indicate a need to establish payment rates for each provider type based on its own unique cost structures.

Therefore, for CY 2011, we are proposing to compute four separate PHP APC per diem payment rates, two for CMHC PHPs (for Level I and Level II services using only CMHC data) and two for hospital-based PHPs (Level I and Level II services using only hospital-based PHP data). Creating the proposed four payment rates (two for CMHC PHPs and two for hospital-based PHPs) would support 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. We request public comments on our proposal to provide four separate PHP APC per diem payment rates, two for CMHC PHPs and two for hospital-based PHPs.

The proposed APCs median per diem costs for PHP services for CY 2011 are as follows:

TABLE 34.—PROPOSED CY 2011 MEDIAN PER DIEM COSTS FOR CMHC PHP SERVICES

Proposed APC	Group Title	Proposed Median Per Diem Costs
0172	Level 1 Partial Hospitalization (3 services) for CMHCs	$118.19
0173	Level II Partial Hospitalization (4 or more services) for CMHCs	$123.35

TABLE 35.—PROPOSED CY 2011 MEDIAN PER DIEM COSTS FOR HOSPITAL-BASED PHP SERVICES

Proposed APC	Group Title	Proposed Median
0175	Level 1 Partial Hospitalization (3 services) for hospital-based PHPs	$184.47
0176	Level II Partial Hospitalization (4 or more services) for hospital-based PHPs	$235.58

We note that this proposal is consistent with the recommendation by several commenters in the CY 2010 OPPS/ASC final rule with comment period that CMS adopt

two additional payment rates that are site specific APCs for PHP services, where the hospital-based PHP APCs for Level I services (3 services) and Level II services (4 or more services) would be established using only hospital-based data and the CMHC PHP APCs for Level I services (3 services) and Level II services (4 or more services) would be established using only CMHC data (74 FR 60557).

C. Proposed Changes to Regulations to Incorporate Provisions of HCERA 2010

As stated in section X.A. of this proposed rule, section 1301 of HCERA 2010 made a change to the statutory definition of a CMHC and a change to the description of what constitutes a PHP. Specifically, section 1301(a) of HCERA 2010 revised the definition of a CMHC set forth at section 1861(ff)(3)(B) of the Act by adding a provision to the existing provisions under which a CMHC, effective on the first day of the first calendar quarter that begins at least 12 months after the date of enactment (that is, April 1, 2011), must provide at least 40 percent of its services to individuals who are not eligible for benefits under Title XVIII of the Act (Medicare). Section 1301(b) of HCERA 2010 amended the description of a PHP to specify that the program must be a distinct and organized intensive ambulatory treatment service offering less than 24-hour daily care "other than in an individual's home or in an inpatient or residential setting."

Our existing regulations at 42 CFR 410.2 incorporate the statutory definitions of "Community mental health center (CMHC)" and "Partial hospitalization services." We are proposing to revise the definition of a CMHC in §410.2 to include the additional requirement provided for under the amendment made by section 1301(a) of HCERA 2010. Under existing §410.2, we define "partial hospitalization services" to mean "a

distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care and furnishes the services described in §410.43." We are proposing to revise this definition to incorporate the amendment made by section 1301(b) of HCERA 2010 to describe partial hospitalization services as a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care "other than in an individual's home or in an inpatient residential setting" and furnishes the services described in §410.43.

D. Proposed Separate Threshold for Outlier Payments to CMHCs

In the November 7, 2003 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.

In CY 2004, the separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs. In CY 2005, the separate outlier threshold for CMHCs resulted in $0.5 million in outlier payments to CMHCs. 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.

As noted in section II.F. of this proposed rule, 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 2011. We are proposing that a portion of that 1.0 percent, an amount equal to 0.04 percent of outlier payments (or 0.0004) percent of total OPPS payments), would be allocated to CMHCs for PHP outliers. As discussed in section II.F. 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 APC is the only APC 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 outliers. As noted in section II.F. of this proposed rule, we are proposing to set the outlier threshold for CMHCs for CY 2011 at 3.40 times the APC payment amount and the CY 2011 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.

XI. Proposed Procedures That Will 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 59856), 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 2011 only as inpatient procedures is included as Addendum E to this proposed rule.

B. Proposed Changes to the Inpatient List

For the CY 2011 OPPS, we are proposing to use the same methodology as 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 three procedures that met the criteria for potential removal from the inpatient list. We then clinically reviewed these three 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 2010 meeting of the APC Panel, we solicited the APC Panel's input on the appropriateness of removing the following three procedures from the CY 2011 inpatient list: CPT codes 21193 (Reconstruction of mandibular rami; horizontal, vertical, C, or L osteotomy; without bone graft); 21395 (Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)); and 25909 (Amputation, forearm, through radius and ulna; reamputation). Following the discussion at its February 2010 meeting, the APC Panel recommended that CMS remove from the CY 2011 inpatient list the three CPT codes that we had identified: CPT codes 21193, 21395, and 25909.

For the CY 2011 OPPS, we are proposing to accept the APC Panel's recommendations to remove the procedures described by CPT codes 21193, 21395, and 25909 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. The three procedures that we are proposing to remove from the inpatient list for CY 2011 and their CPT codes, long descriptors, and proposed APC assignments are displayed in Table 36 below.

TABLE 36.—PROCEDURES PROPOSED FOR REMOVAL FROM THE INPATIENT LIST AND THEIR PROPOSED APC ASSIGNMENTS FOR CY 2011

CPT Code	Long Descriptor	Proposed CY 2011 APC Assignment	Proposed CY 2011 Status Indicator
21193	Reconstruction of mandibular rami; horizontal, vertical, C, or L osteotomy; without bone graft	0256	T
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft	0256	T
25909	Amputation, forearm, through radius and ulna; reamputation	0049	T

XII. Proposed OPPS Nonrecurring Technical and Policy Changes and Clarifications

A. Physician Supervision

1. Background

In the CY 2000 OPPS final rule with comment period (65 FR 18524-18526), we amended our regulations to establish, as a condition of payment, the requirements for physician supervision of diagnostic and therapeutic services provided to hospital outpatients incident to a physician's service. We adopted physician supervision policies as a condition of payment to ensure that Medicare pays for high quality hospital outpatient services provided to beneficiaries in a safe and effective manner and consistent with Medicare requirements. We clarified and restated the various payment requirements for physician supervision of therapeutic and diagnostic services through notice and comment rulemaking 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). In response to concerns about our policy restatement that were expressed following the publication of the CY 2009 final rule with comment period, we met with

stakeholders and further delineated our physician supervision policies for both therapeutic and diagnostic services in the CY 2010 OPPS/ASC proposed rule and final rule with comment period (74 FR 35365 and 74 FR 60679 through 60680, respectively).

While we received and responded to many comments in the course of the CY 2010 rulemaking, addressing supervision for both diagnostic and therapeutic services, it was not until after publication of the CY 2010 OPPS/ASC final rule with comment period that we received substantial comments from the CAH community in response to a technical correction we made to codify our long standing view that CAHs are subject to the supervision policy for payment of therapeutic services in the regulations at 42 CFR 410.27. In addition, the broader hospital community continues to indicate that it would prefer that we modify the current supervision policy to permit a lower level of supervision for therapeutic services.

By way of introduction, we have defined supervision in the hospital outpatient setting by drawing on the three levels of supervision that we defined for the physician office setting at §410.32(b): general, direct and personal supervision. Over time, we have tailored these definitions to apply them in the hospital outpatient setting, but we have maintained the following premises. General supervision means that a service is furnished under the overall direction and control of the physician, but his or her physical presence is not required during the performance of the procedure. Direct supervision means that the physician is physically present on site and is immediately available to furnish assistance and direction throughout the performance of the procedure. However, it does not mean the physician must be present in the same room when the procedure is

being performed. Personal supervision means the physician is present in the room when the service is being performed.

a. Outpatient Therapeutic Services

As set forth in the CY 2000 OPPS final rule with comment period establishing the hospital outpatient prospective payment system, direct supervision is the standard for supervision of hospital outpatient therapeutic services covered and paid by Medicare in hospitals and provider based departments (PBDs) of hospitals. In that rule, we defined "direct supervision" to mean that "the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed." In the CY 2000 OPPS final rule with comment period, we finalized regulation text in §410.27(f) specifying that direct supervision is required in PBDs of hospitals. In the preamble discussion we emphasized the importance of the direct supervision requirement for off-campus provider based departments. We also stated that the language of §410.27(f) "applies to services furnished at an entity that is located off the campus of a hospital that we designate as having provider-based status as a department of a hospital in accordance with §413.65." We disagreed with commenters that the requirement for direct supervision in the off campus provider-based hospital department was more stringent than that required on the hospital campus. We noted that section 1861(s)(2)(B) of the Act authorizes payment for hospital services incident to physicians' services furnished to outpatients. We stated that "we require that hospital services and supplies furnished to outpatients that are incident to physician

services be furnished on a physician's order by hospital personnel and under a physician's supervision" (65 FR 18525). We further stated that "we assume the physician supervision requirement is met on hospital premises because staff physicians would always be nearby within the hospital."

In manual guidance, we have clarified that we expect services incident to physicians' services to be performed under direct supervision. We provide in Section 20.5.1, Chapter 6, of the Medicare Benefit Policy Manual (Pub. 100-04) that services and supplies must be furnished on a physician's order and delivered under supervision. Section 20.5.1 indicates further that each occasion of a service by a nonphysician does not need to also be the occasion of the actual rendition of a personal professional service by the physician responsible for the care of the patient. Nevertheless, as stipulated in that same section of the Manual "during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often enough to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen."

In the CY 2009 OPPS/ASC proposed rule and final rule with comment period, we provided a restatement and clarification of the requirements for physician supervision of hospital outpatient diagnostic and therapeutic services that were set forth in the CY 2000 OPPS final rule with comment period. We chose to restate the existing physician supervision policy for hospital outpatient therapeutic services in part because we were concerned that some stakeholders may have misunderstood our use of the term "assume" in the following statement, "We assume the physician requirement is met on hospital

premises because staff physicians would always be nearby within the hospital. The effect of the regulations in this final rule is to extend this assumption to a department of a hospital that is located on the campus of the hospital" (65 FR 18525). We were concerned that stakeholders might believe that this statement meant that we do not require any supervision in the hospital or in an on-campus PBD for hospital outpatient therapeutic services, or that we only require general supervision for those services.

In our policy restatement in the CY 2009 OPPS/ASC rulemaking, we reiterated that direct supervision is the standard for physician supervision, as set forth in the CY 2000 OPPS final rule with comment period, for supervision of hospital outpatient therapeutic services covered and paid by Medicare in hospitals and PBDs of hospitals. We stated clearly that we expect direct physician supervision of all hospital outpatient therapeutic services, regardless of their on-campus or off-campus location, but indicated that we would continue to emphasize the physician supervision requirements in off-campus PBDs as we did in the CY 2000 OPPS final rule with comment period. We noted that if there were problems with outpatient care in a hospital or in an on-campus PBD where direct supervision was not in place (that is, the expectation of direct supervision was not met), we would consider that to be a quality concern.

After we published the CY 2009 OPPS/ASC final rule with comment period, we received significantly more public feedback than during the rulemaking cycle about our restatement of our supervision policy for both diagnostic and therapeutic services. We met with stakeholders in the early part of 2009 as we prepared for the CY 2010 rulemaking cycle, as well as reviewed all public input that we received, to craft a

response to these concerns regarding the supervision requirements. For therapeutic services, we considered the concerns of various stakeholders along with our position that direct supervision for therapeutic services is appropriate and aligned with the statutory requirement that Medicare only makes payment for therapeutic services in the hospital outpatient setting that are "incident to" physician services.

In the CY 2010 OPPS/ASC final rule with comment period, we finalized our proposal to allow, in addition to clinical psychologists, certain other nonphysician practitioners to directly supervise services that they may perform themselves under their State license and scope of practice and hospital-granted or CAH-granted privileges. The nonphysician practitioners that were permitted to provide direct supervision of therapeutic services under the CY 2010 OPPS/ASC final rule with comment period are physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, and licensed clinical social workers. These nonphysician practitioners may directly supervise outpatient therapeutic services that they may personally furnish in accordance with State law and all additional requirements, including the Medicare coverage rules relating to their services specified in our regulations at 42 CFR 410.71, 410.73, 410.74, 410.75, 410.76, and 410.77 (for example, requirements for collaboration with, or general supervision by, a physician). In implementing the new benefits for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation added by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, Pub. L. 110-275), we required that direct supervision of services furnished in the hospital

outpatient department must be provided by a doctor of medicine or osteopathy as required by statute.

For services furnished on a hospital's main campus, we finalized a modification of our proposed definition of "direct supervision" in new paragraph (a)(1)(iv)(A) of §410.27 that allows for the supervisory physician or nonphysician practitioner to be anywhere on the hospital campus. Therefore, as of CY 2010, direct supervision on the hospital or CAH campus or in an on-campus PBD means that "the supervisory physician or nonphysician practitioner must be present on the same campus and immediately available to furnish assistance and direction throughout the performance of the procedure." Because the term "in the hospital or CAH" applies broadly to "incident to" requirements such as the site-of-service requirement for therapeutic services provided by the hospital directly and under arrangement, we also established a definition of "in the hospital" in new paragraph §410.27(g) as meaning areas in the main building(s) of a hospital or CAH that are under the ownership, financial, and administrative control of the hospital or CAH; that are operated as part of the hospital; and for which the hospital bills the services furnished under the hospital's or CAH's CMS Certification Number (CCN). In the preamble to the CY 2010 OPPS/ASC final rule with comment period, as part of the discussion of various public comments on the definition of the hospital campus, and on the supervision requirement specifically, we stated that we would recognize other areas or structures of the hospital's campus that are not part of the hospital, such as physician offices, rural health centers, skilled nursing facilities, or other entities that participate separately under Medicare to be part of the hospital's campus.

In the CY 2010 OPPS/ASC final rule with comment period, we also finalized our proposal to add paragraph (a)(1)(iv)(B) to §410.27. This paragraph updated our previous regulation at §410.27(f) to reflect that, for off-campus PBDs of hospitals, the physician or nonphysician practitioner must be present in the off-campus PBD, as defined in §413.65, and 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 in the room when the procedure is performed. In addition, we finalized the proposed technical change to clarify the language in §410.27(f) by removing the phrase "present and on the premises of the location" and replacing it with the phrase "present in the off-campus provider-based department."

Finally, we finalized a technical correction to the title of §410.27 to read "Outpatient hospital or CAH services and supplies incident to a physician service: Conditions," to clarify in the title that the requirements for payment of hospital outpatient therapeutic services incident to a physician or nonphysician practitioner service in that section apply to both hospitals and CAHs. Similarly, we included the phrase "hospital or CAH" throughout the text of §410.27 wherever the text referred only to "hospital." We viewed this as a technical correction because the statute applies the same regulations to hospitals and CAHs when appropriate. Specifically, the definition of "hospital" in section 1861(e) of the Act expressly excludes CAHs "unless the context otherwise requires." Accordingly, we do not believe it is necessary for a regulation to reference specifically the applicability to CAHs for those regulations to be appropriate given the "context" for CAHs. Although payment to CAHs is authorized under section 1834(g) of

the Act, many of the payment rules applicable to hospitals paid under sections 1886(d) and 1833(t) of the Act apply to CAHs.

We believe that the supervision requirements should apply in the context of CAHs because they represent appropriate safety and quality requirements for Medicare payment of outpatient services. In the early part of this year, the CAH community asserted that the CAH CoPs offer more flexibility in staffing requirements than the rule requiring direct supervision, and that the CAH CoPs address the general availability of physician and nonphysician practitioners on the CAH campus. The hospital CoPs at 42 CFR 482.22 require hospital medical staff to be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body. They also require 24 hour nursing services that are provided by or supervised by a registered nurse. Under section 1820(c)(2)(B) of the Act, among other criteria, a CAH must meet the same staffing requirements as would apply under section 1861(e) of the Act to a hospital located in a rural area. However, there are some exceptions to these staffing requirements. Section 1820(c)(2)(B)(iv) of the Act specifies that the CAH need not meet hospital staffing requirements under section 1861(e) of the Act regarding the days and hours in which it is open and fully staffed; the facility may provide certain services under arrangement at an off-site location; that inpatient care may be provided by a physician assistant, nurse practitioner, or clinical nurse specialist subject to the oversight of a physician, who need not be present in the facility.

The CAH CoPs in 42 CFR 485.631 are specific in recognizing the statutory authority to be staffed by nonphysician practitioners rather than physicians, provided a

doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates. The requirement that the practitioner "be available" in §485.631 has been interpreted to mean that the nonphysician practitioner or physician is available by phone, but not necessarily physically present on the CAH campus. The CAH CoPs also specify standards for emergency personnel under §485.618, requiring that a doctor of medicine or osteopathy, or a nonphysician practitioner such as a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, be on call and immediately available by telephone or radio contact, and available on site within 30 minutes, on a 24-hour a day basis in most areas.

However, in the Medicare program, payment requirements are frequently different from those identified in the CoPs because the two sets of rules serve very separate and distinct purposes. CoPs apply largely at the facility level, while payment regulations apply at the service level. Payment regulations, such as requirements for how contracted entities providing services to hospital patients, support program goals of appropriate and accurate payment for quality services. In contrast, for all providers including CAHs, the CoPs authorize hospitals to participate in the Medicare program. We establish CoPs as minimum standards for patient health and safety, and CoPs focus on creating a foundation to ensure quality and safe care for beneficiaries throughout a given facility, irrespective of the payment system or service provided. CoPs do not ensure that payment is appropriate for specific types of purchased services nor can they substitute for payment requirements since that is not their function.

In summary, requirements established for purposes of payment frequently differ from the requirements established by the CoPs for many providers, including hospitals and CAHs. Whereas payment regulations establish basic parameters defining the services being purchased, CoPs (including both the hospital CoPs and the CAH CoPs) establish standards to ensure a minimum level of quality and safety for operating as a hospital or a CAH. The minimum standards established as CoPs are not always adequate to address the particular quality, safety and other requirements for payment for a service or group of services.

b. Outpatient Diagnostic Services

As we stated in the CY 2009 OPPS/ASC and CY 2000 OPPS proposed rules and final rules with comment period, section 1861(s)(2)(C) of the Act authorizes payment for diagnostic services that are furnished to a hospital outpatient for the purpose of diagnostic study. We have further defined the requirements for diagnostic services furnished to hospital outpatients, including requirements for physician supervision of diagnostic services, in §§410.28 and 410.32 of our regulations. For CY 2010, we finalized a proposal to require that all hospital outpatient diagnostic services provided directly or under arrangement, whether provided in the hospital, in a PBD of a hospital, or at a nonhospital location, follow the physician supervision requirements for individual tests as listed in the MPFS Relative Value File in order to receive payment. The existing definitions of general and personal supervision as defined in §§410.32(b)(3)(i) and (b)(3)(iii) also apply. For services furnished directly or under arrangement in the hospital or on-campus PBD, “direct supervision” means that the physician must be present on the

same campus and immediately available to furnish assistance and direction throughout the performance of the procedure. For the purposes of §410.28, as for the general purposes of §410.27, the definition of "in the hospital" as incorporated in §410.27(g) applies.

These policies are an extension of the supervision requirements for outpatient diagnostic tests performed in a provider-based department that were adopted at the inception of the OPPS in the CY 2000 OPPS final rule with comment period. The MPFS Relative Value File is updated quarterly and is available on the CMS Web site at: http://www.cms.gov/PhysicianFeeSched/ . For diagnostic services not listed in the MPFS, we have indicated that Medicare contractors, in consultation with their medical directors, would define appropriate supervision levels in order to determine whether claims for these services are reasonable and necessary.

We note that the current requirement in §§410.28(e)(1) and (e)(2) that physician supervision of diagnostic services provided in the hospital or in any provider-based department follow the levels for diagnostic services established under the MPFS explicitly applies to hospitals that are paid pursuant to section 1833(t) of the Act, which is the statutory authority for the OPPS. Because Medicare makes payments to CAHs pursuant to section 1834(g) of the Act, at this time, CAHs are not subject to this supervision requirement.

2. Issues Regarding the Supervision of Hospital Outpatient Services Raised by Hospitals and Other Stakeholders

Following the adoption of our policies in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60575 through 60591), beginning in January 2010, we began to receive a sizable amount of correspondence, as well as numerous phone calls, and questions through other public avenues, including the regular open door forum calls, from the rural hospital and CAH community indicating its belief that the requirement for direct supervision for therapeutic services finalized in that rule is at odds with longstanding and prevailing practice in rural communities. These hospitals and their representatives stated that they generally function with a reduced level of supervision for the provision of therapeutic services and that while they furnish services under a physician's or appropriate nonphysician practitioner's order, frequently no physician or nonphysician practitioner is physically present anywhere in the CAH or small rural hospital while the therapeutic services are being furnished. CAHs, in particular, noted that the provisions in their CoPs allow a CAH to operate under the reduced staffing requirements specified above. Specifically, under the CoPs, CAHs must have a physician or one of several types of nonphysician practitioners available by phone at all times, but not on campus, and in most areas of the country, for emergencies, the CAH must have a physician or certain other nonphysician practitioners with training or experience in emergency care physically available onsite within 30 minutes.

Both CAHs and rural hospitals have stated that the flexibility to allow nonphysician practitioners to supervise services that we authorized in the CY 2010

OPPS/ASC final rule with comment period is helpful for meeting the direct supervision requirement for all therapeutic services, but that a shortage of qualified practitioners in rural areas continues to make it difficult to staff a physician or nonphysician practitioner for supervision purposes. They also noted that a practitioner retained on the campus of a small rural hospital or CAH to meet supervision requirements may not have other patients or medical activities to complete. In an urban or large urban hospital, a practitioner would be able to see other patients or engage in other activities so long as those activities could be interrupted, such that they would be immediately available to supervise.

In a series of questions and answers about supervision on the CMS Web site (http://www.cms.gov/HospitalOutpatientPPS/05_OPPSGuidance.asp#TopOfPage), we provided additional guidance regarding our regulations about who can supervise services in order to explain to CAHs and small rural hospitals the flexibility we believe exists within our requirement for direct supervision. For example, in that document, we state that we believe the emergency physician or non-physician practitioner, who would be the most likely practitioners staffing a small rural hospital or CAH, can directly supervise outpatient services so long as the emergency physician in the emergency department of the campus meets the other requirements of direct supervision. That is, the individual needs to be immediately available, so that, if needed, he or she could reasonably be interrupted to furnish assistance and direction in the delivery of therapeutic services provided elsewhere in the hospital. We believe that most emergency physicians can appropriately supervise many services within the scope of their knowledge, skills,

licensure, and hospital-granted privileges, including observation services. With regard to whether an emergency physician or a nonphysician practitioner could be interrupted, such that the individual could be immediately available, we have stated that each hospital would need to assess the level of activity in their emergency department and determine whether at least one emergency physician or nonphysician practitioner could be interrupted to furnish assistance and direction in the treatment of outpatients.

In their correspondence and discussion in public forums, CAHs and small rural hospitals explicitly have raised concerns about services that extend after regular operating hours, especially observation services. They also 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 typically, including IV hydration, blood transfusions, and chemotherapy. They stated that their facilities have protocols to safely deliver all of these services, including chemotherapy, relying on nursing or other hospital staff to provide the service and having a physician or non-physician practitioner available by phone to furnish assistance and direction throughout the duration of the therapeutic service.

In the early part of this year, 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 lasted for an extended period of time. In response to rising concerns among the rural community about these rules and the inability of some hospitals to meet the direct supervision

requirement, we issued a statement on March 15, 2010, indicating that we would not enforce the rules for supervision of hospital outpatient therapeutic procedures furnished in CAHs in CY 2010 (http://www.cms.gov/HospitalOutpatientPPS/01_overview.asp#TopOfPage). We also stated that we would proactively revisit the rules surrounding the supervision of services furnished by CAHs in the CY 2011 OPPS/ASC proposed rule.

With regard to diagnostic services, unlike supervision of therapeutic services, we have had only limited dialogue with various stakeholders about our CY 2010 policy to recognize the supervision levels for diagnostic services under the MPFS for the provision of diagnostic services in the hospital. Individual stakeholders have asked about supervision of specific diagnostic services and have noted that our requirement that the hospitals follow the supervision levels for diagnostic services in the hospital identified in the MPFS Relative Value Unit file has required some modest changes in hospital staffing practices. We also have received questions requesting clarification about related supervision requirements for nonphysician practitioners. We note that adopting the supervision levels defined under the MPFS for diagnostic services in 42 CFR 410.32 means that nonphysician practitioners that are not specifically excluded under §410.32(b) from the level of supervision required by the MPFS are subject to supervision by a physician at the level of supervision required by the diagnostic test. We also discussed in our CY 2010 OPPS/ASC final rule with comment period that diagnostic X-ray and other diagnostic tests must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act (74 FR 60588 through 60590).

3. Proposed Policies for Supervision of Outpatient Therapeutic Services in Hospitals and CAHs

As indicated in our March 15, 2010 statement, we are revisiting the issue of supervision of outpatient therapeutic services in CAHs to ensure a robust public discussion about supervision requirements for payment in hospital outpatient departments, including those located in rural communities, and CAH outpatient departments. In this proposed rule, we are proposing modest changes to our supervision policy for therapeutic services that reflect our continuing commitment to require direct supervision for the provision of therapeutic services in the hospital outpatient setting as a requirement for payment. We are proposing these changes for all hospitals, including CAHs, because we believe that Medicare should purchase a basic quality of service for all Medicare beneficiaries. Specifically, we are proposing to identify a limited set of services with a significant monitoring component that can extend for a sizable period of time, that are not surgical, and that typically have a low risk of complication after assessment at the beginning of the service, as "nonsurgical extended duration therapeutic services." We are proposing for these services that there would be a requirement for direct supervision for the initiation of the service followed by general supervision for the remainder of the service. We are proposing to adopt the definition of "general supervision" in §410.32(b)(3)(i), which is the same definition of general supervision that we already recognize as appropriate for diagnostic services with a general supervision level requirement under the MPFS. Finally, at the end of this proposal, we include

several discussion points designed to focus public comments and generate sufficient detail to assist us in crafting a final policy.

In the CY 2010 OPPS/ASC final rule with comment period, we affirmed our belief that direct supervision is the appropriate supervision requirement for therapeutic services provided in the hospital outpatient setting. In that rule, we finalized a definition of direct supervision in the hospital or in an on-campus department of the hospital to mean that the physician or nonphysician practitioner is present on the same campus and immediately available to furnish assistance and direction throughout the performance of the procedure (74 FR 60591).

In considering the significant correspondence from CAHs and rural communities, as well as public discussion on the issue of supervision through the open door forum and calls with individual hospitals and other hospital representatives, we sought to identify some means of offering flexibility within the supervision requirement to hospitals and CAHs, while continuing to ensure that Medicare purchases services delivered with a basic level of quality and safety and also fulfills the statutory requirement for payment of therapeutic outpatient services in the hospital that are provided "incident to" physician services. We recognize the concerns of CAHs and rural hospitals that it could be difficult to staff a physician or nonphysician practitioner on the campus of the CAH or small rural hospital to supervise services that have a significant monitoring component and lack an active component being performed by the physician or nonphysician practitioner, especially when these services extend into after business hours or overnight. CAHs and rural hospitals explicitly identified observation services, IV hydration, chemotherapy, and

blood transfusions as the services that are particularly challenging to provide under direct supervision. Observation services, in particular, can extend for a significant period of time. Data from the 85X claims indicate that most observation care lasts longer than 12 hours and almost all such care ends within 48 hours, suggesting that observation care frequently extends after business hours and through the night.

We recognize that any service with an extended duration and a significant monitoring component could challenge hospitals' ability to ensure direct supervision, and we decided to concentrate on these services. We set out to identify services with a significant monitoring component extending after business hours as identified by the CAHs and hospitals in rural communities and for which we could offer some flexibility in meeting the requirement for direct supervision of therapeutic services without compromising the quality and safety of services for which Medicare makes payment. One way to provide flexibility would be to allow a reduced level of supervision for part of these services. CAHs have already stated that their longstanding practice has been to provide therapeutic services under general supervision, which comports with the minimum requirements set forth in their CoPs to participate in the Medicare program that a physician or certain nonphysician practitioner must be available by phone but not physically present on the CAH campus. As defined in §410.32(b)(3)(i), "general supervision" means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. We have established a requirement for direct supervision for all hospital outpatient services in our CY 2000 and CY 2010 rulemaking processes. However, we

reasoned that, for certain extended duration services, we could adopt a general supervision requirement for some portion of the service, as long as we believed that such flexibility would not undermine the quality and safety of purchased services. Therefore, we are proposing to require, for a limited set of nonsurgical extended duration therapeutic services, direct supervision during the initiation of the service followed by general supervision for the remainder of the service.

We are proposing to define "initiation of the service" as the beginning portion of a service ending when the patient is stable and the supervising physician or appropriate nonphysician practitioner believes the remainder of the service can be delivered safely under their general direction and control without their physical presence on the hospital campus or in the PBD of the hospital. We considered further defining the term "stable" in this definition as there is an established definition in the EMTALA regulations at section 489.24(b). In those regulations, "stabilized" with respect to an emergency medical condition means "that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer for the individual from a facility …." However, this language is set within the context of emergency services, not hospital outpatient therapeutic services generally, and we have been clear that supervision is more than emergency response. Ultimately, we were not certain that this definition would be appropriate for a payment requirement for supervision of outpatient therapeutic services.

We also are not proposing to further define the term "initiation" or to set time limits on this portion of the service because we believe that the determination that a

patient is sufficiently stable to transfer from direct supervision to general supervision, and the timing of that decision, are clinical judgments. Because some of the services identified for this proposed policy have the potential for shorter durations, such as an hour, we believe it is best to leave the determination of when to move from direct to general supervision to the discretion of the supervising physician or nonphysician practitioner. However, we are considering whether the point of transfer from direct supervision to general supervision should be documented in the medical record or identified in a hospital protocol, and we invite public comment on how CMS might review the physician or nonphysician practitioner's decision to move from direct to general supervision to monitor for proper billing should an adverse event occur.

We considered four criteria when identifying the list of services to which this new policy of direct supervision during the initiation of the service followed by general supervision for the remainder of the service would apply. We first accepted the two criteria identified in correspondence and discussion with CAHs and rural hospitals, that the service be of extended duration, frequently extending beyond normal business hours, and that the service largely consist of a significant monitoring component typically conducted by nursing or other auxiliary staff. We added a third criterion that the service must be of sufficiently low risk, such that the service typically would not require direct supervision often during the service. We believe this criterion is appropriate because, as we have previously discussed, our requirement for direct supervision is grounded the statutory "incident to" payment authority, as well as the need to ensure that Medicare purchases services that represent a basic level of quality and safety. We have noted that,

unlike an inpatient admission, the provision of outpatient services lacks certain safeguards such as a detailed medical history and a plan of care (74 FR 60578 through 60588). Finally, we excluded all surgical services including recovery time from potential inclusion because, although monitoring of any patient in recovery is a key component of surgery, it is not the focus or a substantial component of the service and because we believe the surgeon should personally evaluate the patient's medical status during the recovery period.

Using these four criteria, we identified a list of nonsurgical therapeutic services that have a tendency to last for a long period of time, that largely consist of monitoring, and that have a low risk that the physician's physical presence will be needed once the patient is stable. To identify this list of potential services, we reviewed all medical services, including the services and procedures specifically identified by CAHs and rural hospitals in their correspondence and public discussion. The proposed list of nonsurgical extended duration therapeutic services appears in Table 37 below. We explicitly did not include chemotherapy or blood transfusions in our proposed list of nonsurgical extended duration therapeutic services because we believe that these services require the physician's or nonphysician practitioner's recurrent physical presence in order to evaluate the patient's condition in the event it is necessary to redirect the service.

We included observation services on the proposed list of nonsurgical extended duration services. In Section 20.6 of Chapter 2 of the Medicare Benefit Policy Manual (Pub. 100-02), we define observation care as "a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and

reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital." Therefore, the acuity of patients receiving observation services and the amount of recurrent supervisory review that may be necessary for these services can vary significantly. Observation services can be of low acuity and can have a low probability that the supervising physician or nonphysician practitioner's physical presence would be needed to step in and perform the service or otherwise furnish assistance. We do note in Section 290.5.1 of Chapter 4 of the Medicare Claims Processing Manual (Pub. 100-04) that, for observation services, (a) "the beneficiary must be in the care of a physician during the period of observation, as documented in the medical record by outpatient registration, discharge, and other appropriate progress notes that are timed, written, and signed by the physician, and (b) the medical record also must include documentation that the physician explicitly assessed patient risk to determine that the beneficiary would benefit from observation services." We would continue to expect hospitals and CAHs to fulfill these specific requirements associated with observation care, so the supervising physician or appropriate nonphysician practitioner must continue to evaluate the patient periodically and include written notes in the medical record.

TABLE 37.--PROPOSED LIST OF NONSURGICAL EXTENDED DURATION THERAPEUTIC SERVICES

HCPCS Code	Long Description
C8957	Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than 8 hours), requiring use of portable or implantable pump
G0378	Hospital observation service, per hour
G0379	Direct admission of patient for hospital observation care

HCPCS Code	Long Description
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour
96361	Intravenous infusion, hydration; each additional hour (List separately in addition to code for primary procedure)
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion, up to 1 hour (List separately in addition to code for primary procedure)
96368	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion (List separately in addition to code for primary procedure)
96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)
96370	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
96371	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)
96376	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (List separately in addition to code for primary procedure)

In summary, we are proposing to require direct supervision as defined in §410.27(a)(1)(iv) during an initiation period, followed by a minimum standard of general supervision as defined in §410.32(b)(3)(i) for the duration of the service, for a limited set of "nonsurgical extended duration therapeutic services" identified in Table 37 above. We are proposing to add a new paragraph (a)(1)(v) to §410.27 for this provision. In new

§410.27(a)(1)(v)(A), we are proposing to define "nonsurgical extended duration therapeutic services" as services that can last a significant period of time, have a substantial monitoring component, have a low risk of requiring the physician's or appropriate nonphysician practitioner's physical presence to furnish assistance and direction after the initiation of the service, and are not primarily surgical in nature. In new §410.27(a)(1)(v)(B), we are proposing to define "initiation of the service" as the beginning portion of a service ending when the patient is stable and the supervising physician or appropriate nonphysician practitioner believes the remainder of the service can be delivered safely under his or her general direction and control without needing his or her physical presence on the hospital campus or in the PBD of the hospital. We note that in the CY 2010 OPPS/ASC final rule with comment period, in presenting the regulation text changes for §410.27, paragraph (a)(2) (relating to PHP services) was inadvertently deleted from the Code of Federal Regulations. We are proposing to restore paragraph (a)(2) as it originally appeared in the regulations.

In crafting this proposal, we considered other avenues to offer flexibility within our requirement for direct supervision. We summarize below the alternatives we considered in order to focus public comments and generate sufficient detail to assist us in developing the final policy. In addition to considering the proposed policy to permit general supervision after an initial period of direct supervision for a limited subset of services, we also considered offering hospitals the flexibility to broaden the list to include chemotherapy and blood transfusions, which some stakeholders also maintain do not require direct supervision. Because we were concerned that these services had a high

probability of needing a physician or nonphysician practitioner to redirect the service, we reasoned that we would have to require hospitals to create internal guidelines specifying a supervision level and protocols for staffing that supervision level for every nonsurgical extended duration therapeutic service. We considered proposing minimum requirements for these internal supervision guidelines, including annual review and approval by a governing committee, periodic internal evaluation of implementation, and the ability to make these guidelines available to Medicare program auditors if requested. Further, these guidelines would be reviewed thoroughly by CMS should a quality issue arise. Given the complexity of services such as chemotherapy and blood transfusions, and the probability that the physician's or nonphysician practitioner's physical presence will be required during the service, we decided to propose a policy to ensure greater safety for these higher acuity services. We also chose not to pursue this internal guidelines option because we believed that hospitals would find these requirements onerous and that the policy would not necessarily provide the flexibility that CAHs and rural hospitals desire. We are seeking public comment on whether hospitals agree with our assessment about the challenge of crafting, maintaining, and implementing internal guidelines about supervision and whether general supervision is clinically appropriate and safe for chemotherapy, blood transfusions, and similar services.

We also considered whether for payment purposes we should explicitly exclude outpatient CAH services from all supervision requirements. As discussed above, one of the grounds for applying the direct supervision requirement to outpatient therapeutic services furnished in hospitals is that these services are outpatient hospital services

furnished “incident to” physicians' services under section 1861(s)(2)(B) of the Act and paid under the OPPS pursuant to section 1833(t) of the Act. In contrast, "outpatient critical access hospital services" are defined under section 1861(mm)(3) of the Act, and CAHs are reimbursed for outpatient CAH services based on their reasonable costs pursuant to section 1834(g) of the Act. We believe that outpatient CAH services are correctly viewed as being furnished “incident to” physicians' services.

Section 1861(mm)(3) of the Act defines “outpatient critical access hospital services” as “medical and other health services furnished by a critical access hospital on an outpatient basis.” The term “medical and other health services” is defined at section 1861(s) of the Act as including “hospital services . . . incident to physicians’ services rendered to outpatients.” Furthermore, the same considerations regarding the need to ensure that services furnished to Medicare beneficiaries represent a basic level of quality and safety that apply to outpatient hospital services are equally applicable to outpatient CAH services. As a result, we believe it is appropriate to apply the same supervision requirements to outpatient therapeutic services furnished in hospitals and CAHs. We acknowledge that statutory provisions allow CAHs some flexibility in their staffing requirements to operate with more nursing staff and nonphysician practitioners rather than physicians if those are the practitioners that are available, and that our regulations recognize those reduced staffing requirements in the CoPs by establishing that, at a minimum, the physician or nonphysician practitioner must be available, but not necessarily on the CAH campus. Some have suggested, however, that these regulations which establish only minimal requirements reduce the quality and safety of CAH services

and that CAHs should be required to disclose their reduced staffing levels to patients prior to providing services. Accordingly, we have elected not to propose to exempt CAHs from all direct supervision requirements because we believe that Medicare should purchase from CAHs services that are of the same basic level of safety and quality as from other hospitals, and because we also believe that both small rural hospitals paid under the OPPS through section 1833(t) of the Act and CAHs paid at reasonable cost under section 1834(g) of the Act have similar staffing and resource constraints. In fact, given that CAHs are reimbursed based on their reasonable costs, we reasoned that CAHs might be better able to hire staff to provide direct supervision. We welcome public comment on the topic of exempting CAHs from a direct supervision requirement for outpatient therapeutic services, including comments in response to our concerns about making such a proposal.

4. Supervision of Hospital Outpatient Diagnostic Services

We have received limited correspondence and questions on our policy finalized in the CY 2010 OPPS/ASC final rule with comment period to adopt for outpatient hospital diagnostic services the physician supervision levels in §410.32(b)(3) established under the MPFS and indicated on the Practice Expense Relative Value Unit file. As discussed above, the CY 2010 policy applies to hospitals and not to CAHs. However, we have received questions asking whether nonphysician practitioners previously performing diagnostic tests without physician supervision, within their State scope of practice and hospital-granted privileges, can continue to perform those tests without physician supervision. The CY 2010 policy now requires physician supervision of those services,

unless the nonphysician practitioner is specifically exempted under §410.32(b)(2) or there is some other provision addressing supervision for that type of nonphysician practitioner. As part of a broader proposal addressing clinical nurse-midwives as defined in §410.77(b)(2) of the regulations, we are making a clarifying proposal in the CY 2011 MPFS proposed rule that clinical nurse-midwives should be excepted from requiring physician supervision for the diagnostic tests that they are authorized to perform under applicable State laws. Comments on that proposal should be submitted through the comment process for that proposed rule (CMS-1503-P).

B. Proposed Payment for Preventive Services

1. Definition of "Preventive Services"

Section 4104(a) of the Affordable Care Act revised section 1861(ddd) of the Act by adding a new paragraph (3), which defines the term "preventive services." Preventive services are defined as:

- Screening and preventive services currently described in section 1861(ww)(2) of the Act, except for electrocardiograms described in section 1861(ww)(2)(M) of the Act;

- An initial preventive physical examination (IPPE) as defined in section 1861(ww) of the Act; and

- Personalized prevention plan services (PPPS), also known as the "Annual Wellness Visit," as defined in section 1861(hhh) of the Act (which was added by section 4103 of the Affordable Care Act).

The services specified in the definition of "preventive services" at section 1861(ddd)(3)(A) of the Act, as cross-referenced to section 1861(ww)(2) of the Act, excluding electrocardiograms, include the following:

- Pneumococcal, influenza, and hepatitis B vaccine and administration.
- Screening mammography.
- Screening pap smear and screening pelvic examination.
- Prostate cancer screening tests.
- Colorectal cancer screening tests.
- Diabetes outpatient self-management training (DSMT).
- Bone mass measurement.
- Screening for glaucoma.
- Medical nutrition therapy (MNT) services.
- Cardiovascular screening blood tests.
- Diabetes screening tests.
- Ultrasound screening for abdominal aortic aneurysm (AAA).
- Additional preventive services identified for coverage through the national coverage determination (NCD) process.

We note that currently the only additional preventive service identified for coverage through the NCD process is HIV testing. A proposed national coverage determination for smoking cessation services for asymptomatic patients (CAG-00420N, "Proposed Coverage Decision Memorandum for Counseling to Prevent Tobacco Use"), was released in May 2010 on the CMS Web site at:

http://www.cms.gov/mcd/index_list.asp?list_type=nca. We will address the applicability of section 4104 of the Affordable Care Act to these services if an NCD establishing them as additional preventive services is finalized before the CY 2011 OPPS/ASC final rule with comment period is issued.

We are specifying our proposals to implement the coverage and payment provisions for PPPS in the CY 2011 Medicare Physician Fee Schedule (MPFS) proposed rule. Therefore, public comments on the proposed coverage of and payment for PPPS under the provisions of the Affordable Care Act should be submitted in response to the CY 2011 MPFS proposed rule. The implementing regulations regarding coverage of the IPPE are already established under existing 42 CFR 410.16 and remain unchanged by the Affordable Care Act. As discussed below in section XII.B.2. of this proposed rule, we are presenting our proposals for the application or waiver of the coinsurance requirements and the deductible for preventive services as provided for under sections 4104(b) and (c) of the Affordable Care Act.

2. Coinsurance and Deductible for Preventive Services

Sections 4104(b) and 10406 of the Affordable Care Act amended section 1833(a)(1) of the Act to require 100 percent payment for the IPPE and for those preventive services 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. This requirement waives any coinsurance or copayment that would otherwise be applicable under section 1833(a)(1) of the Act for those items and services listed in section 1861(ww)(2) of the Act (excluding electrocardiograms) to

which the USPSTF has given a grade of A or B. In addition, section 4103(c) of the Affordable Care Act waives the coinsurance or copayment for the annual wellness visit providing PPPS. The coinsurance or copayment represents the beneficiary's share of the payment to the provider or supplier for furnished services. Coinsurance generally refers to a percentage (for example, 20 percent) of the Medicare payment rate for which the beneficiary is liable and is applicable under the MPFS and ASC payment system, while copayment generally refers to an established amount that the beneficiary must pay that is not necessarily related to a particular percentage of the Medicare payment rate, and is applicable under the OPPS. We refer readers to the CY 2011 MPFS proposed rule for the proposed provisions related to payment for preventive services, including waiver of the deductible and copayment, under the MPFS, and to section XV.D.1.d. of this proposed rule for our proposals to implement the provisions related to payment for preventive services under the ASC payment system.

Section 4104(c) of the Affordable Care Act amended section 1833(b)(1) of the Act to waive the Part B deductible for preventive services described in section 1861(ddd)(3)(A) of the Act that have a grade of A or B from the USPSTF. In addition, section 4103(c)(4) of the Affordable Care Act waives the Part B deductible for the annual wellness visit providing PPPS. These provisions are effective for services furnished on and after January 1, 2011. We note that section 101(b)(2) of the MIPPA previously amended section 1833(b) of the Act to waive the deductible for the IPPE, effective January 1, 2009.

Not all preventive services described in paragraph (A) of section 1861(ddd)(3) of the Act are recommended by the USPSTF with a grade of A or B, and therefore, some of the preventive services do not meet the criteria in sections 1833(a)(1) and 1833(b)(1) of the Act for the waiver of deductible and coinsurance. However, the changes made by section 4104 of the Affordable Care Act do not affect most of the pre-existing specific provisions listed in existing §410.160(b) and §410.152 of the regulations (which reflect the provisions found in sections 1833(a) and 1833(b) of the Act) that waive the deductible and coinsurance for specific services. For example, section 1833(a)(1)(D) of the Act waives the coinsurance and section 1833(b)(3) of the Act waives the deductible for clinical laboratory tests (including those furnished for screening purposes). Section 4104 of the Affordable Care Act does not change this provision and the waiver for both the deductible and coinsurance remains in place for all laboratory tests, regardless of whether the particular clinical laboratory test meets the criteria of section 4104 for waiver of deductible and coinsurance as a preventive service.

The following preventive services listed in section 1833(ddd)(3)(A) of the Act are not recommended by the USPSTF with a grade of A or B for any indication or population: digital rectal examination provided as a prostate cancer screening service; glaucoma screening; diabetes outpatient self-management training; and barium enema provided as a colorectal cancer screening service.

Specifically, HCPCS code G0102 (Prostate cancer screening; digital rectal exam), which does not have a grade of A or B from the USPSTF for any indication or population, will continue to be subject to the deductible and coinsurance. However, the

deductible and coinsurance for HCPCS code G0103 (Prostate cancer screening; prostate specific antigen test (PSA)) will continue to be waived under section 1833(a)(1)(D) of the Act as a clinical laboratory test, even though it also does not have a grade of A or B from the USPSTF.

Glaucoma screening services, described by HCPCS codes G0117 (Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist) and G0118 (Glaucoma screening for high risk patient furnished under the direct supervision of an optometrist or ophthalmologist), will continue to be subject to the deductible and coinsurance requirements because these services are not recommended with a grade of A or B by the USPSTF for any indication or population. Similarly, diabetes outpatient self-management training is currently not rated by the USPSTF; therefore, the deductible and coinsurance requirements will continue to apply.

Barium enemas provided as colorectal cancer screening tests, described by HCPCS codes G0106 (Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema) and G0120 (Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema) do not have a grade of A or B from the USPSTF for any indication or population. However, the deductible does not apply to barium enemas provided as colorectal cancer screening tests, because colorectal cancer screening tests are explicitly excluded from the deductible under section 1833(b)(8) of the Act. However, there is no specific exclusion of barium enemas from the coinsurance requirement at section 1833(b)(1) of the Act. Therefore, this requirement, as applicable, continues to apply to barium enemas. We note that the USPSTF has given a grade of A

to colonoscopy, flexible sigmoidoscopy, and fecal occult blood screening tests, and that, as a result, these services qualify for the statutory waiver of both the deductible and coinsurance.

We also note that the USPSTF ceased to make recommendations with regard to vaccines and vaccine administration after CY 1996, so as not to conflict with the recommendations of the CDC's Advisory Committee on Immunization Practices. However, the USPSTF's most recent vaccine recommendations, which were never withdrawn by the USPSTF, gave a grade of B to the influenza and pneumococcal vaccines and their administration and a grade of A to the hepatitis B vaccine and its administration. While sections 1833(a)(1) and 1833(b)(1) of the Act require that the preventive services receive a grade of A or B from the USPSTF for the coinsurance and deductible to be waived, the statute does not specify that the recommended grade must be furnished within any given timeframe. The USPSTF grades for these preventive services are the most current USPSTF grade and have never been withdrawn. Therefore, we believe that these preventive services meet the requirements of the statute for the waiver of the deductible and coinsurance. We also note that the CDC's Advisory Committee on Immunization Practices currently recommends influenza, pneumococcal, and hepatitis B vaccines.

Table 38 below displays the HCPCS codes (paid under the OPPS or at reasonable cost) that we are proposing as "preventive services" under section 1861(ddd)(3)(A) of the Act. Table 38 also provides the most recent USPSTF grade, if any, that is the basis for our proposed policy with regard to waiver of the deducible and coinsurance, as

applicable. In developing recommendations regarding preventive services, we recognize that the USPSTF may make recommendations that are specific to an indication or population, at times including characteristics such as gender and age in its recommendations. While we are proposing to waive the deductible and coinsurance for any Medicare covered preventive service recommended with a grade of A or B for any indication or population, with no limits on the indication or population as long as the USPSTF has recommended the preventive service for at least one indication and/or population with a grade of A or B, we note that all existing Medicare coverage policies for such services, including any limitations based on indication or population, continue to apply. In some cases, national coverage policies may currently limit Medicare coverage based on the indication or population, consistent with the USPSTF recommendations with a grade of A or B for the indication or population. In other cases where Medicare does not explicitly noncover preventive services for a specific population or indication, we would expect that, particularly in those cases where the USPSTF recommendation grade is a D (that is, the USPTF recommends against the service because there is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits), practitioners would only order those preventive services that are clinically appropriate for the beneficiary. If we have future concerns about the appropriateness of preventive services for an indication or population in light of the USPSTF's recommendations, we may consider using our authority under section 1834(n)(1) of the Act (as added by section 4105 of the Affordable Care Act) to modify Medicare coverage of any preventive service consistent with the recommendations of the USPSTF.

We note that section 4103(c)(3)(A) of the Affordable Care Act excludes the PPPS from payment under the OPPS and establishes payment for the PPPS when performed in a hospital outpatient department under the MPFS. In this OPPS/ASC proposed rule, we are proposing to add a new §419.22(t) to the regulations to specify that the PPPS is excluded from payment under the OPPS. In the process of revising the regulations to reflect the exclusion of PPPS from the OPPS, we noticed the need for existing §419.21(e) to be updated to reflect that an IPPE may be performed within 12 months after the date of the individual's initial enrollment in Part B effective January 1, 2009. We also noticed that existing §419.22(m) of the regulations should be updated to reflect that a revised payment methodology for end-stage renal disease (ESRD) services will go into effect on January 1, 2011. Therefore, we also are proposing to revise §§419.21(e) and 419.22(m). We refer readers to the CY 2011 MPFS proposed rule for a discussion of the proposed changes to §410.160(b) and §410.152 of the regulations to implement the provisions related to the definition of preventive services and the waiver of the coinsurance and deductible for preventive services as specified by sections 4103 and 4104 of the Affordable Care Act.

TABLE 38.--PROPOSED CY 2011 DEDUCTIBLE AND COINSURANCE FOR OPPS PREVENTIVE SERVICES UNDER SECTION 1861(ddd)(3)(A) OF THE ACT* (INCLUDES THE INITIAL PREVENTIVE PHYSICAL EXAMINATION (IPPE))

Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating[1]	CY 2010 Coinsurance Deductible	CY 2011 Coinsurance Deductible

Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating[1]	CY 2010 Coinsurance Deductible	CY 2011 Coinsurance Deductible
Initial Preventive Physical Examination (IPPE)	G0402	Initial preventive physical examination; face to face visits, services limited to new beneficiary during the first 12 months of Medicare enrollment	***Not Rated**	Coinsurance applies and deductible is waived	Waived
	G0404	Electrocardiogram, routine ECG with 12 leads; tracing only, without interpretation and report, performed as a screening for the initial preventive physical examination		Not Waived	Not Waived
Ultrasound Screening for Abdominal Aortic Aneurysm (AAA)	G0389	Ultrasound, B-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) ultrasound screening	B	Coinsurance applies and deductible is waived	Waived
Screening Pap Test	Q0091	Screening papanicolaou smear; obtaining, preparing and conveyance of cervical or vaginal smear to laboratory	A	Coinsurance applies and deductible is waived	Waived
Screening Pelvic Exam	G0101	Cervical or vaginal cancer screening; pelvic and clinical breast examination	A	Coinsurance applies and deductible is waived	Waived
Bone Mass Measurement	G0130	Single energy x-ray absorptiometry (sexa) bone density study, one or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)	B	Not Waived	Waived
	77078	Computed tomography, bone mineral density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)		Not Waived	Waived

Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating[1]	CY 2010 Coinsurance Deductible	CY 2011 Coinsurance Deductible
	77079	Computed tomography, bone mineral density study, 1 or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)		Not Waived	Waived
	77080	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)		Not Waived	Waived
	77081	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)		Not Waived	Waived
	77083	Radiographic absorptiometry (eg, photodensitometry, radiogrammetry), 1 or more sites		Not Waived	Waived
	76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method		Not Waived	Waived
Colorectal Cancer Screening	G0104	Colorectal cancer screening; flexible sigmoidoscopy	A	Coinsurance applies and deductible is waived	Waived
	G0105	Colorectal cancer screening; colonoscopy on individual at high risk		Coinsurance applies and deductible is waived	Waived
	G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk		Coinsurance applies and deductible is waived	Waived
	G0106	Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema	***Not Rated**	Coinsurance applies and deductible is waived	Coinsurance applies and deductible is waived

Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating[1]	CY 2010 Coinsurance Deductible	CY 2011 Coinsurance Deductible
	G0120	Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema.		Coinsurance applies and deductible is waived	Coinsurance applies and deductible is waived
Prostate Cancer Screening	G0102	Prostate cancer screening; digital rectal examination	D	Not Waived	Not Waived
Glaucoma Screening	G0117	Glaucoma screening for high risk patients furnished by an optometrist or ophthalmologist	I	Not Waived	Not Waived
	G0118	Glaucoma screening for high risk patient furnished under the direct supervision of an optometrist or ophthalmologist		Not Waived	Not Waived
Influenza Virus Vaccine	90655	Influenza virus vaccine, split virus, preservative free, when administered to children 6-35 months of age, for intramuscular use	B	Waived	Waived
	90656	Influenza virus vaccine, split virus, preservative free, when administered to individuals 3 years and older, for intramuscular use		Waived	Waived
	90657	Influenza virus vaccine, split virus, when administered to children 6-35 months of age, for intramuscular use		Waived	Waived
	90658	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use		Waived	Waived

Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating[1]	CY 2010 Coinsurance Deductible	CY 2011 Coinsurance Deductible
	90660	Influenza virus vaccine, live, for intranasal use		Waived	Waived
	90662	Influenza virus vaccine, split virus, preservative free, enhanced immunogenicity via increased antigen content, for intramuscular use		Waived	Waived
	G0008	Administration of influenza virus vaccine		Waived	Waived
	G9141	Influenza a (h1n1) immunization administration (includes the physician counseling the patient/family)		Waived	Waived
	G9142	Influenza a (h1n1) vaccine, any route of administration		Waived	Waived
Pneumo-coccal Vaccine	90669	Pneumococcal conjugate vaccine, polyvalent, when administered to children younger than 5 years, for intramuscular use	B	Waived	Waived
	90670	Pneumococcal vacc, 13 val im		Waived	Waived
	90732	Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, when administered to individuals 2 years or older, for subcutaneous or intramuscular use		Waived	Waived
	G0009	Administration of pneumococcal vaccine		Waived	Waived

Service	CPT/ HCPCS Code	Long Descriptor	USPSTF Rating[1]	CY 2010 Coinsurance Deductible	CY 2011 Coinsurance Deductible
Hepatitis B Vaccine	90740	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (3 dose schedule), for intramuscular use	A	Not Waived	Waived
	90743	Hepatitis B vaccine, adolescent (2 dose schedule), for intramuscular use		Not Waived	Waived
	90744	Hepatitis B vaccine, pediatric/adolescent dosage (3 dose schedule), for intramuscular use		Not Waived	Waived
	90746	Hepatitis B vaccine, adult dosage, for intramuscular use		Not Waived	Waived
	90747	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (4 dose schedule), for intramuscular use		Not Waived	Waived

*This table lists only the preventive services, as defined by the Affordable Care Act, that are paid under the OPPS or at reasonable cost, and excludes preventive services such as screening mammography and cardiovascular screening blood tests that are paid under another fee schedule such as the MPFS or the Clinical Laboratory Fee Schedule. A listing of all services defined by the Affordable Care Act as preventive services can be found in the CY 2011 MPFS proposed rule. We note that any preventive service must meet the Medicare coverage guidelines for the service including being appropriate to the beneficiary to whom it is being furnished.

[1] **U.S. Preventive Services Task Force Recommendations:**
A -- The USPSTF strongly recommends that clinicians routinely provide [the service] to eligible patients. (The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.)
B -- The USPSTF recommends that clinicians routinely provide [the service] to eligible patients. (The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.)
C -- The USPSTF makes no recommendation for or against routine provision of [the service]. (The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.)
D -- The USPSTF recommends against routinely providing [the service] to asymptomatic patients. (The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.)
I -- The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. (Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.)

3. Extension of Waiver of Deductible to Services Furnished in Connection with or in Relation to a Colorectal Cancer Screening Test That Becomes Diagnostic or Therapeutic

Section 4104(c) of the Affordable Care Act amended section 1833(b) of the Act to waive the Part B deductible for colorectal cancer screening tests that become diagnostic. Specifically, section 4104(c)(2) of the Affordable Care Act waives the deductible with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test.

We are proposing that all surgical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema be viewed as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test. We believe that this interpretation is appropriate because we believe that it would be very rare for an unrelated surgery to occur on the same date as one of these scheduled screening tests. Moreover, we believe that the risk of improper expenditures would be very small under this policy because it is the deductible, and not the coinsurance, that is waived for the related procedures other than the screening tests. In the event of a legislative change to this policy (for example, a statutory change that would waive the coinsurance for these related services in addition to the deductible), we would reassess the appropriateness of this proposed definition of services that are furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test that becomes diagnostic. We also note that the annual

deductible would likely be met when any surgical procedure (related or not) is performed on the same day as the scheduled screening test.

We are proposing to implement this provision by creating a HCPCS modifier that providers would append to the diagnostic procedure code that is reported instead of the screening colonoscopy or screening flexible sigmoidoscopy HCPCS code or as a result of the barium enema when the screening test becomes a diagnostic service. The claims processing system would respond to the modifier by waiving the deductible for all surgical services on the same date as the diagnostic test. Coinsurance or copayment would continue to apply to the diagnostic test and to other services furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

C. Payment for Pulmonary Rehabilitation, Cardiac Rehabilitation, and Intensive Cardiac Rehabilitation Services Furnished to Hospital Outpatients

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60566 through 60574), we addressed the provisions of section 144(a) of the Medicare Improvements for Patients and Providers Act (MIPPA, Pub. L. 110-275). Section 144(a) provided for Medicare Part B coverage and payment for pulmonary and cardiac rehabilitation services furnished to beneficiaries with chronic obstructive pulmonary disease and certain other conditions, effective January 1, 2010. Medicare Part B coverage is provided for items and services under a cardiac rehabilitation (CR) program, a pulmonary rehabilitation (PR) program, and an intensive cardiac rehabilitation (ICR) program furnished in a physician's office, a hospital on an outpatient basis, or in other settings as the Secretary determines appropriate. We have received questions as to whether a CAH outpatient department is a

covered setting for services furnished under these programs because the amendments made to the Act by section 144(a) of the MMA do not specifically define CAHs as hospitals for this benefit.

In this proposed rule, we are clarifying that a CAH outpatient department is considered a covered setting for PR, CR and ICR programs, provided that the programs meet all of the regulatory requirements, including, but not limited to, direct supervision of all services by a physician, specified in 42 CFR 410.27(a)(1)(iv)(A) and 410.47(a)(2)(ii). We can establish that CAHs are a covered setting because the law and implementing regulations specify that PR, CR and ICR services are covered in the hospital outpatient setting, and we define a hospital outpatient in the regulations and program instructions as "a person . . . who . . . receives services . . .directly from the hospital or CAH" (42 CFR 410.2 and the Medicare Benefit Policy Manual, Chapter 6, Section 20.2, available at the CMS Web site at: http://www.cms.gov/manuals/Downloads/bp102c06.pdf). We also note that under section 1861(e) of the Act, the context of the term "hospital" as used in the coverage provisions for PR, CR and ICR reflects the inclusion of CAHs.

D. Expansion of Multiple Procedure Reduction under the Medicare Physician Fee Schedule (MPFS) to Therapy Services

Hospitals are paid for outpatient physical therapy (which includes speech language pathology services) and outpatient occupational therapy under the Medicare Physician Fee Schedule (MPFS). Outpatient physical therapy (which includes speech language pathology services) and outpatient occupational therapy services, as described in section 1833(a)(8) of the Act, are excluded from the OPPS by section 1833(t)(1)(B)(iv)

of the Act. Section 1833(a)(8) of the Act provides that outpatient physical and occupational therapy are to be paid as provided in section 1834(k)of the Act. Section 1834(k)(3) of the Act specifies that these services are paid under the fee schedule established under section 1848 of the Act and section 1848 of the Act establishes payment under the MPFS.

For CY 2011, we are proposing to revise the MPFS to apply a multiple procedure reduction to payment for all outpatient physical and occupational therapy services paid under the MPFS. This proposal is contained in the CY 2011 MPFS proposed rule (CMS-1503-P, Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2011). To be considered in the development of the final policy for CY 2011, public comments on this issue should be submitted in response to the CY 2011 MPFS proposed rule.

XIII. 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. Our proposed CY 2011 status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule.

For CY 2011, we are not proposing to make any changes to the status indicators that were listed in Addendum D1 of the CY 2010 OPPS/ASC final rule with comment

period. These status indicators are listed in the tables under sections XIII.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.
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.

Indicator	Item/Code/Service	OPPS Payment Status
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 service. (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.

Section 142 of Pub. L. 110-275 (MIPPA) required CMS to pay for therapeutic radiopharmaceuticals for the period of July 1, 2008, through December 31, 2009, at hospitals' charges adjusted to the costs. The status indicator "H" was assigned to therapeutic radiopharmaceuticals to indicate that an item was paid at charges adjusted to cost during CY 2009. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60593), we changed our policy to pay prospectively and separately for therapeutic radiopharmaceuticals with average per day costs greater than the CY 2010 drug packaging threshold of $65 under the OPPS. Therefore, we changed the status indicator for HCPCS codes used to report separately payable therapeutic radiopharmaceuticals

from “H” to “K,” which indicated that an item is separately paid under the OPPS at the APC payment rate established for the item. We refer readers to section V.B.5. of the CY 2010 OPPS/ASC final rule with comment period for discussion of the final CY 2010 changes to our payment policy for therapeutic radiopharmaceuticals (74 FR 60593). For CY 2011 OPPS, we are proposing to continue to pay for therapeutic radiopharmaceuticals under the OPPS at the APC payment rate established for the item. (We refer readers to our discussion of this proposal for payment of therapeutic radiopharmaceuticals in section V.B.3. of this proposed rule.)

For CY 2010, we established a policy to consider implantable biologicals that are not on pass-through status as a biological before January 1, 2010, as devices for pass-through evaluation and payment beginning in CY 2010. Therefore, pass-through implantable biologicals were assigned a status indicator of “H,” while nonpass-through implantable biologicals were assigned a status indicator of “N” beginning in CY 2010. Those implantable biologicals that have been granted pass-through status under the drug and biological criteria prior to January 1, 2010, continued to be assigned a status indicator of “G” until they are proposed for expiration from pass-through status during our annual rulemaking cycle. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60593), we assigned status indicator "K" to nonimplantable biologicals and adjusted the definition of status indicator "K" accordingly. For CY 2011, we are not proposing any changes to current policy. We discuss our proposed treatment of drugs, biologicals, and radiopharmaceuticals with new or continuing pass-through status in CY 2011 in section V.A.3. of this proposed rule, and we discuss our proposed treatment

of drugs and biologicals with expiring pass-through status in CY 2010 including the specific implantable biologicals to which this policy is proposed to apply for CY 2011 OPPS in section V.A.2. of this proposed rule.

The proposed CY 2011 status indicators are displayed in both the table above and in Addendum D1 to this proposed rule.

2. Proposed Payment Status Indicators to Designate Services That Are Paid under a Payment System Other Than the OPPS

We are not proposing any changes to the status indicators listed below for the CY 2011 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.
	● 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.
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 2011 status indicators displayed in the table above are also displayed in Addendum D1 to this proposed rule.

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 any changes to the status indicators listed below for the CY 2011 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 are also displayed in Addendum D1 to this proposed rule.

4. Proposed Payment Status Indicators to Designate Services That Are Not Payable by Medicare on Outpatient Claims

We are not proposing any changes to the payment status indicators listed below for the CY 2011 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	

Addendum B, with a complete listing of HCPCS codes including proposed payment status indicators for each code and proposed APC assignments for CY 2011, is available electronically on the CMS Web site under supporting documentation for this proposed rule at:

http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/list.asp#TopOfPage.

B. Proposed Comment Indicator Definitions

For the CY 2011 OPPS, we are proposing to use the same two comment indicators that are in effect for the CY 2010 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 2011 compared to their assignment as of June 30, 2010. 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 2011. The use of the comment indicator "CH" in association with a composite APC indicates that we have proposed a change to the configuration of the composite APC in this proposed rule.

We are proposing to use the "CH" comment indicator in the CY 2011 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 2011 compared to their assignment as of December 31, 2010.

We are not proposing any changes to our policy regarding the use of comment indicator "NI." In our CY 2010 OPPS/ASC final rule with comment period, we expanded the definition of comment indicator "NI" to include an existing code with a substantial revision to its code descriptor in the next calendar year as compared to the current calendar year to indicate that the code's CY 2010 OPPS treatment was open to public comment on the CY 2010 OPPS/ASC final rule with comment period.

In the CY 2010 OPPS/ASC final rule with comment period, there are numerous instances in which the descriptor of a previously existing Category I CPT code was substantially revised for the next calendar year so that it described a new service or

procedure that could have been assigned a new code number by the CPT Editorial Panel and that new code number would then had been assigned the "NI" comment indicator. We anticipate that, for CY 2011, not all new services or procedures will be assigned a new CPT code number, but instead will be described by an existing CPT code number with a substantially revised code descriptor. We are proposing to continue to assign the comment indicator "NI" to these codes in order to allow for comment on our proposed payment for these substantially revised codes. Like all codes labeled with comment indicator "NI," in a final rule, we will respond to public comments and finalize their OPPS treatment in the CY 2012 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 2011 will also be labeled with comment indicator "NI" in Addendum B to the CY 2011 OPPS/ASC final rule with comment period.

Only HCPCS codes with comment indicator "NI" in the CY 2011 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 2011 OPPS/ASC final rule with comment period will not be open to public comment, unless we specifically have requested additional comments elsewhere in the final rule with comment period. The CY 2011 treatment of HCPCS codes that appears in the CY 2011 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 final rule with comment period.

We are not proposing any changes to the definitions of the OPPS comment indicators for CY 2011. Their proposed definitions are listed in Addendum D2 to this proposed rule.

XIV. 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 2010 MedPAC "Report to Congress: Medicare Payment Policy" included the following recommendation relating specifically to the Medicare hospital OPPS:

Recommendation 2A-1: The Congress should increase payment rates for the acute inpatient and outpatient prospective payment systems in 2011 by the projected rate of increase in the hospital market basket index, concurrent with implementation of a quality incentive payment program.

CMS Response: Subsequent to the issuance of the MedPAC report, Congress enacted the Affordable Care Act. Section 1833(t)(3)(F) as added by section 3401 of the Affordable Care Act and as amended by section 10319 of the Affordable Care Act and section 1105 of the HCERA provides that after determining the OPD fee schedule increase factor, the Secretary shall reduce such increase factor by 0.25 percentage point

in 2011. As discussed in section II.B. of this proposed rule, we are proposing to increase the full CY 2011 conversion factor by the projected rate of increase in the hospital market basket less the mandated 0.25 percentage point reduction. Simultaneously, we are proposing for CY 2011 to reduce the annual update factor by 2.0 percentage points for hospitals that are defined under section 1886(d)(1)(B) of the Act and that do not meet the hospital outpatient quality data reporting required by section 1833(t)(17) of the Act. We would make this adjustment after the application of the 0.25 percentage point reduction. For the adjustment under section 1833(t)(17) of the Act, we are proposing to calculate two conversion factors: a full conversion factor based on the annual update factor, adjusted by the 0.25 percentage point reduction required by the Affordable Care Act for CY 2011; and a reduced conversion factor that reflects the 2.0 percentage points reduction to the annual update factor, as adjusted by the 0.25 percentage point reduction. CMS implemented the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) in CY 2008 and is proposing to continue this program in CY 2011 (as discussed in section XVI. of this proposed rule).

The full March 2010 MedPAC report can be downloaded from MedPAC's Web site at: http://www.medpac.gov/documents/Mar10_EntireReport.pdf.

B. APC Panel Recommendations

Recommendations made by the APC Panel at its February 2010 meeting are discussed in the sections of this proposed rule that correspond to topics addressed by the APC Panel. The report and recommendations from the APC Panel's February 17-18, 2010 meeting 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. As of the publication of the proposed rule, there were no OIG reports that resulted in OIG recommendations for OPPS policy changes for CY 2011.

XV. 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 5103 of the Deficit Reduction Act of 2005 (DRA), Pub. L. 109-171, amended section 1833(i)(2) of the Act by adding new subparagraph (E) to place a limitation on payment amounts for surgical procedures furnished in ASCs on or after January 1, 2007, but before the effective date of the revised ASC payment system (that is, January 1, 2008). Section 1833(i)(2)(E) of the Act provides that if the standard overhead amount under section 1833(i)(2)(A) of the Act for an ASC facility service for such

surgical procedures, without application of any geographic adjustment, exceeds the Medicare payment amount under the hospital OPPS for the service for that year, without application of any geographic adjustment, the Secretary shall substitute the OPPS payment amount for the ASC standard overhead amount.

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)(2)(D) of the Act, in part, by redesignating clause (iv) as clause (v) and adding a new clause (iv) and by adding new section 1833(i)(7)(A). These amendments provide the Secretary the authority to require ASCs to submit data on quality measures and to reduce the annual update by 2 percentage points for an ASC that fails to submit data as required by the Secretary on selected quality measures. Section 109(b) of the MIEA-TRHCA also amended section 1833(i) of the Act by adding new section 1833(i)(7)(B), which requires that, to the extent the Secretary establishes such an ASC quality reporting program, certain quality of care reporting requirements mandated for hospitals paid under the OPPS, under sections 1833(t)(17)(B), (C), (D) and (E) of the Act, as added by section 109(a) of the MIEA-TRHCA, be applied in a similar manner to ASCs unless otherwise specified by the Secretary.

Sections 4104 and 10406 of the Affordable Care Act amend sections 1833(a)(1) and (b)(1) of the Act to waive the coinsurance and the Part B deductible for those preventive services 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 amends 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 amends 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 HCPCS and CPT codes under the ASC payment system. This policy is consistent with the OPPS to the extent possible (72 FR 42533). Additionally, 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 an 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 would 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 noncovered 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, consequently, were corrected in a correction notice to that final rule with comment period (74 FR 65449). We also are publishing a second correction notice in the **Federal Register** around the time of this proposed rule 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. Finally, we are publishing a notice around the time of this proposed rule 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 ACA. It also reflects technical changes to the ASC payment rates announced in prior correction notices.

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. Patient safety and health outcomes continue to be important to us as more health care moves to the ambulatory care setting. Therefore, as we gain additional experience with the ASC

payment system, we are interested in any information the public may have regarding the comparative patient outcomes of surgical care provided in ambulatory settings, including HOPDs, ASCs, and physicians' offices, particularly with regard to the Medicare population.

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 below in section XV.B., 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), just as we do for

the OPPS. 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 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 39 below, we summarize our proposed process for updating the HCPCS codes recognized under the ASC payment system.

TABLE 39.—PROPOSED COMMENT TIMEFRAME FOR NEW HCPCS CODES

OPPS/ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April l, 2010	Level II HCPCS Codes	April 1, 2010	CY 2011 OPPS/ASC proposed rule	CY 2011 OPPS/ASC final rule with comment period
July 1, 2010	Level II HCPCS Codes	July 1, 2010	CY 2011 OPPS/ASC proposed rule	CY 2011 OPPS/ASC final rule with comment period
	Category I (certain vaccine codes) and III CPT codes	July 1, 2010	CY 2011 OPPS/ASC proposed rule	CY 2011 OPPS/ASC final rule with comment period
October 1, 2010	Level II HCPCS Codes	October 1, 2010	CY 2011 OPPS/ASC final rule with comment period	CY 2012 OPPS/ASC final rule with comment period
January 1, 2011	Level II HCPCS Codes	January 1, 2011	CY 2011 OPPS/ASC final rule with comment period	CY 20112 OPPS/ASC final rule with comment period
	Category I and III CPT Codes	January 1, 2011	CY 2011 OPPS/ASC final rule with comment period	CY 2012 OPPS/ASC final rule with comment period

This process is discussed in detail below and we have separated our discussion based on whether we are proposing to solicit public comments in this CY 2011 proposed rule on a specific group of the CPT and Level II HCPCS codes (and respond to those comments in the CY 2011 OPPS/ASC final rule with comment period) or whether we are proposing to solicit public comments on another specific group of the codes in the CY 2011 final rule with comment period (and respond to those comments in the CY 2012 OPPS/ASC final rule with comment period). We sought public comments in the

CY 2010 OPPS/ASC final rule with comment period on the new CPT and HCPCS codes that were effective January 1, 2010. These new codes were flagged with comment indicator "N1" in Addendum AA and BB to the CY 2010 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 2010 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 2011 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 2010 for which We Are Soliciting Public Comments in this Proposed Rule

In the April and July CRs, we made effective for April 1 or July 1, 2010, a total of 14 new Level II HCPCS codes and 7 new Category III CPT codes that were not addressed in the CY 2010 OPPS/ASC final rule with comment period. (We note that one Level II HCPCS code, C9262, that was added in the April 2010 CR, was deleted June 30, 2010 and replaced with Q2025 effective July 1, 2010). The 13 new Level II HCPCS codes describe covered ancillary services.

Through the April 2010 ASC quarterly update (Transmittal 1943, CR 6866, dated April 6, 2010), we added six new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 40, these included HCPCS codes C9258 (Injection, telavancin, 10 mg), C9259 (Injection, pralatrexate, 1 mg), C9260

(Injection, ofatumumab, 10 mg), C9261 (Injection, ustekinumab, 1 mg), C9262 (Fludarabine phosphate, oral, 1 mg), and C9263 (Injection, ecallantide, 1 mg).

Through the July 2010 quarterly update (Transmittal 1984, Change Request 7008, dated June 11, 2010), we are adding seven new drug and biological Level II HCPCS codes to the list of covered ancillary services. Specifically, as displayed in Table 41, we provide separate payment for HCPCS codes C9264 (Injection, tocilizumab, 1 mg), C9265 (Injection, romidepsin, 1 mg), C9266 (Injection, collagenase clostridium histolyticum, 0.1 mg), C9267 (Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO), C9268 (Capsaicin, patch, 10cm2), C9367 (Skin substitute, Endoform Dermal Template, per square centimeter), and Q2025 (Fludarabine phosphate oral, 10mg). As noted above, HCPCS code C9262 was made effective April 1, 2010, and deleted June 30, 2010, when it was replaced with HCPCS code Q2025.

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 to indicate that they are separately paid when provided in ASCs. In this CY 2011 OPPS/ASC proposed rule, we are soliciting public comment on the proposed CY 2010 ASC payment indicators and payment rates for the drugs and biologicals, as listed in Tables 40 and 41below. Those HCPCS codes became payable in ASCs, beginning in April or July 2010, 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 codes listed in Table 40 are included in Addendum BB to this proposed rule. (We note that Level II HCPCS code C9262 was deleted June 30, 2010, and replaced with Q2025 effective July 1, 2010, and therefore is not included in Addendum BB and is not open to public comment. Instead, Level II HCPCS code Q2025 is open for public comment.)

However, because HCPCS codes that become effective for July (listed in Table 41) are not available to us in time for incorporation into the Addenda to the OPPS/ASC proposed rule, our policy is to include these HCPCS codes and their proposed payment indicators and payment rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. These codes and their final payment indicators and rates will be included in the appropriate Addendum to the CY 2011 OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2010 ASC quarterly update CR and their proposed CY 2011 payment rates (based on July 2010 ASP data) that are displayed in Table 41 are not included in Addendum BB to this proposed rule. We are proposing to include these services reported using the new Level II HCPCS codes displayed in Tables 40 and 41 as covered ancillary services for payment to ASCs for CY 2011. The final list of covered ancillary services and the associated payment weights and payment indicators will be included in Addendum BB to the CY 2011 OPPS/ASC final rule with comment period, consistent with our annual update policy.

TABLE 40.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN APRIL 2010

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 Payment Indicator

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 Payment Indicator
C9258	Injection, telavancin, 10 mg	K2
C9259	Injection, pralatrexate, 1 mg	K2
C9260	Injection, ofatumumab, 10 mg	K2
C9261	Injection, ustekinumab, 1 mg	K2
C9262*	Fludarabine phosphate, oral, 1 mg	D5
C9263	Injection, ecallantide, 1 mg	K2

*Level II HCPCS code C9262 was deleted June 30, 2010, and replaced with Q2025 effective July 1, 2010. Because Addendum BB to this proposed rule is based on the codes effective in April, C9262 appears as having a proposed payment indicator of "K2."

TABLE 41.—NEW LEVEL II HCPCS CODES FOR COVERED ANCILLARY SERVICES IMPLEMENTED IN JULY 2010

CY 2010 HCPCS Code	CY 2010 Descriptor	Proposed CY 2011 Payment Indicator	Proposed CY 2011 ASC Payment Rate*
C9264	Injection, tocilizumab, 1 mg	K2	$3.52
C9265	Injection, romidepsin, 1 mg	K2	$223.78
C9266	Injection, collagenase clostridium histolyticum, 0.1 mg	K2	$382.78
C9267	Injection, von Willebrand factor complex (human), Wilate, per 100 IU VWF: RCO	K2	$122.07
C9268	Capsaicin, patch, 10cm2	K2	$11.18
C9367	Skin substitute, Endoform Dermal Template, per square centimeter	K2	$4.35
Q2025**	Fludarabine phosphate oral, 10mg	K2	$8.18

* Based on July 2010 ASP information.
**Level II HCPCS code Q2025 replaced C9262.

Through the July 2010 quarterly update CR, we also implemented ASC payment for seven new Category III CPT codes and one new Level II HCPCS code as ASC covered surgical procedures, effective July 1, 2010. These codes are listed in Table 42 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 the Addenda to the OPPS/ASC final rule with comment period. The new mid-year codes for the covered surgical procedures implemented in July 2010 are displayed in Table 42 below, along with their proposed payment indicators and proposed payment rates. These codes and their final payment indicators and rates will be included in Addendum AA to the CY 2011 OPPS/ASC final rule with comment period.

TABLE 42.—NEW CATEGORY III CPT CODES AND LEVEL II HCPCS CODE IMPLEMENTED IN JULY 2010 AS ASC COVERED SURGICAL PROCEDURES

CY 2010 CPT Code	CY 2010 Long Descriptor	Proposed CY 2011 Payment Indicator**	Proposed CY 2011 ASC Payment Rate
0226T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed	R2*	$26.78
0227T	Anoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)	R2*	$231.07
0228T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; single level	G2	$288.11
0229T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; each additional level (List separately in addition to code for primary procedure)	G2	$148.93
0230T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level	G2	$288.11

CY 2010 CPT Code	CY 2010 Long Descriptor	Proposed CY 2011 Payment Indicator**	Proposed CY 2011 ASC Payment Rate
0231T	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; each additional level (List separately in addition to code for primary procedure)	G2	$148.93
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed	R2*	$26.78
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies	R2*	$177.60

* If designation is temporary.
**Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. At the time this proposed rule is being finalized for publication, current law authorizes a negative update to the MPFS payment rates for CY 2011. Therefore, this proposed rule reflects a negative update to the MPFS payment rates for CY 2011. If Congress revises the MPFS update for CY 2011, we will recalculate the ASC payment rates using the revised update factor in the CY 2011 OPPS/ASC final rule with comment period.

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 2010 through the respective quarterly update CRs. These codes are listed in Tables 40, 41, and 42 of this proposed rule. We are proposing to finalize their payment indicators and their payment rates, if applicable, in the CY 2011 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 2011 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. Specifically, 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 2011.

For CY 2011, we are proposing to include in Addenda AA and BB to the CY 2011 OPPS/ASC final rule with comment period the new Category I and III CPT codes effective January 1, 2011 (including those Category III CPT codes that were released by the AMA in July 2010) that would be incorporated in the January 2011 ASC quarterly update CR and the new Level II HCPCS codes, effective October 1, 2010 or January 1, 2011, that would be released by CMS in its October 2010 and January 2011 ASC quarterly update CRs. These codes would be flagged with comment indicator ''NI'' in Addenda AA and BB to the CY 2011 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 2011 OPPS/ ASC final rule with comment period and would be finalized in the CY 2012 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 are proposing to update the list of ASC covered surgical procedures by adding five procedures to the list. These five procedures were among those excluded from the ASC list for CY 2010 because we believed they did not meet the definition of a covered surgical procedure based on our expectation that they would pose a significant safety risk to Medicare beneficiaries or would require an overnight stay if performed in ASCs. We conducted a review of all HCPCS codes that currently are paid under the OPPS, but not included on the ASC list of covered surgical procedures, to determine if changes in technology and/or medical practice changed the clinical appropriateness of these procedures for the ASC setting. We determined that these five procedures could be safely performed in the ASC setting and are therefore proposing to include them on the list of ASC covered surgical procedures for CY 2011.

The five procedures that we are proposing to add to the ASC list of covered surgical procedures, including their HCPCS code long descriptors and proposed CY 2010 payment indicators, are displayed in Table 43 below.

TABLE 43.—PROPOSED NEW ASC COVERED SURGICAL PROCEDURES FOR CY 2011

CY 2010 HCPCS Code	CY 2010 Long Descriptor	Proposed CY 2011 ASC Payment Indicator*
37204	Transcatheter occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method, non-central nervous system, non-head or neck	G2
37205	Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel	P3
37206	Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; each additional vessel (list separately in addition to code for primary procedure)	P3
37210	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed (Do not report 52649 with 52000, 52276, 52281, 52601, 52647, 52648, 53020, 55250)	P3
50593	Uterine fibroid embolization (ufe, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the procedure	P2

*Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. At the time this proposed rule is being finalized for publication, current law authorizes a negative update to the MPFS payment rates for CY 2011. Therefore, this proposed rule reflects a negative update to the MPFS payment rates for CY 2011. If Congress revises the MPFS update for CY 2011, we will recalculate the ASC payment rates using the revised update factor in the CY 2011 OPPS/ASC final rule with comment period.

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 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 or permanently office-based after taking into account updated volume and utilization data.

(2) Proposed Changes to Covered Surgical Procedures Designated as Office-Based for CY 2011

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 2009 volume and utilization data and the clinical characteristics for all surgical procedures that are assigned payment indicator "G2" in CY 2010, as well as for those procedures assigned one of the temporary office-based payment indicators, specifically "P2*," "P3*," or "R2*" in the CY 2010 ASC final rule with comment period (74 FR 60605 through 60608). We also examined the data for the five procedures that we are proposing to add to the ASC list of covered surgical procedures for CY 2011 (listed in Table 43 above) to determine if these procedures should be designated as office-based.

Our review of the CY 2009 volume and utilization data resulted in our identification of six 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 six procedures we are proposing to permanently designate as office-based are listed in Table 44 below. We note that four of these procedures are procedures that we also are proposing to add to the ASC list of covered surgical procedures for CY 2011: CPT code 37205; CPT code 37206; CPT code 37210; and CPT

code 50593. The other two procedures are already on the ASC list of covered surgical procedures.

TABLE 44.—ASC COVERED SURGICAL PROCEDURES PROPOSED FOR OFFICE-BASED DESIGNATION FOR CY 2011

CY 2010 HCPCS Code	CY 2010 Long Descriptor	CY 2010 ASC Payment Indicator	Proposed CY 2011 ASC Payment Indicator*
20697	Application of multiplane (pins or wires in more than one plane), unilateral, external fixation with stereotactic computer-assisted adjustment (eg, spatial frame), including imaging; exchange (ie, removal and replacement of strut, each	G2	P2
27767	Closed treatment of posterior malleolus fracture; without manipulation	G2	P2
37205	Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel	X5	P3
37206	Transcatheter placement of an intravascular stent(s), (except coronary, carotid, and vertebral vessel), percutaneous; each additional vessel (list separately in addition to code for primary procedure)	X5	P3
37210	Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed (Do not report 52649 with 52000, 52276, 52281, 52601, 52647, 52648, 53020, 55250)	X5	P3
50593	Uterine fibroid embolization (ufe, embolization of the uterine arteries to treat uterine fibroids, leiomyomata), percutaneous	X5	P2

CY 2010 HCPCS Code	CY 2010 Long Descriptor	CY 2010 ASC Payment Indicator	Proposed CY 2011 ASC Payment Indicator*
	approach inclusive of vascular access, vessel selection, embolization, and all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the procedure		

*Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. At the time this proposed rule is being finalized for publication, current law authorizes a negative update to the MPFS payment rates for CY 2011. Therefore, this proposed rule reflects a negative update to the MPFS payment rates for CY 2011. If Congress revises the MPFS update for CY 2011, we will recalculate the ASC payment rates using the revised update factor in the CY 2011 OPPS/ASC final rule with comment period.

We also reviewed CY 2009 volume and utilization data and other information for the six procedures proposed for temporary office-based status in the CY 2010 OPPS/ASC proposed rule (74 FR 35382) and finalized for temporary office-based status in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60607). Among these six procedures, there were almost no claims data for three procedures: CPT code 0099T (Implantation of intrastromal corneal ring segments); CPT code 0124T (Conjunctival drug placement); 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 2011. We also are proposing to maintain in CY 2011 the temporary office-based designation for the four codes that became effective in the July 2010 ASC quarterly update: CPT code 0226T (Angoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including

collection of specimen(s) by brushing or washing when performed); CPT code 0227T (Angoscopy, 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); and HCPCS code C9800 (Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies), because no data are available for these codes at this time.

As a result of our review of the remaining three procedures that have temporary office-based designations for CY 2010 for which we do have claims data, we are proposing to make permanent the office based designations for all of them for CY 2011. The three surgical procedure codes are: CPT code 46930 (Destruction of internal hemorrhoid(s) by thermal energy (e.g., infrared coagulation, cautery, radiofrequency)); CPT code 64455 (Injection(s), anesthetic agent and/or steroid, plantar common digital nerve(s) (eg, Morton's neuroma)); and CPT code 64632 (Destruction by neurolytic agent; plantar common digital nerve). The volume and utilization data for these CPT codes are sufficient to support our determination that these procedures are performed predominantly in physicians' offices. Therefore, we are proposing to make permanent the office-based designations for the 3 procedures for CY 2011.

The procedures that we are proposing to permanently designate as office-based for CY 2011 that were temporarily designated as office-based procedures in CY 2010 are displayed in Table 45 below. The procedures that we are proposing to temporarily designate as office-based for CY 2011 are displayed in Table 46 below. The procedures

for which the proposed office-based designation for CY 2011 is temporary also are indicated by an asterisk in Addendum AA to this proposed rule.

TABLE 45.—CY 2010 TEMPORARILY DESIGNATED OFFICE-BASED ASC COVERED SURGICAL PROCEDURES PROPOSED FOR PERMANENT OFFICE-BASED FOR CY 2011

CY 2010 HCPCS Code	CY 2010 Long Descriptor	CY 2010 ASC Payment Indicator	Proposed CY 2011 ASC Payment Indicator**
46930	Destruction of internal hemorrhoid(s) by thermal energy (e.g., infrared coagulation, cautery, radiofrequency)	P3*	P3
64455	Injection(s), anesthetic agent and/or steroid, plantar common digital nerve(s) (e.g., Morton's neuroma)	P3*	P3
64632	Destruction by neurolytic agent; plantar common digital nerve	P3*	P3

* If designation is temporary.
**Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. At the time this proposed rule is being finalized for publication, current law authorizes a negative update to the MPFS payment rates for CY 2011. Therefore, this proposed rule reflects a negative update to the MPFS payment rates for CY 2011. If Congress revises the MPFS update for CY 2011, we will recalculate the ASC payment rates using the revised update factor in the CY 2011 OPPS/ASC final rule with comment period.

TABLE 46.—CY 2010 TEMPORARILY DESIGNATED OFFICE-BASED ASC COVERED SURGICAL PROCEDURES PROPOSED FOR TEMPORARY OFFICE-BASED DESIGNATION IN CY 2011

CY 2010 HCPCS Code	CY 2010 Long Descriptor	CY 2010 ASC Payment Indicator	Proposed CY 2011 ASC Payment Indicator**
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*

CY 2010 HCPCS Code	CY 2010 Long Descriptor	CY 2010 ASC Payment Indicator	Proposed CY 2011 ASC Payment Indicator**
0226T	Angoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); diagnostic, including collection of specimen(s) by brushing or washing when performed	P2*	R2*
0227T	Angoscopy, high resolution (HRA) (with magnification and chemical agent enhancement); with biopsy(ies)	P2*	R2*
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed	P2*	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*
C9800	Dermal injection procedure(s) for facial lipodystrophy syndrome (LDS) and provision of Radiesse or Sculptra dermal filler, including all items and supplies	R2*	R2*

* If designation is temporary.
**Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the MPFS proposed rates. At the time this proposed rule is being finalized for publication, current law authorizes a negative update to the MPFS payment rates for CY 2011. Therefore, this proposed rule reflects a negative update to the MPFS payment rates for CY 2011. If Congress revises the MPFS update for CY 2011, we will recalculate the ASC payment rates using the revised update factor in the CY 2011 OPPS/ASC final rule with comment period.

Displayed in Table 47 below are new (or substantially revised) CY 2010 HCPCS codes to which we assigned temporary office-based payment indicators in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60608). As explained in section XV.B.1. of that final rule with comment period (74 FR 60599 and 60607), we reviewed all of the newly created HCPCS codes that became available after the issuance of the CY 2009 OPPS/ASC proposed rule that are used to report surgical procedures in

CY 2010 to evaluate their appropriateness for the ASC list of covered surgical procedures. Of the procedures reported by new or substantially revised CY 2010 HCPCS codes that we determined should not be excluded from the ASC list based on our clinical review, including assessment of available utilization and volume data for any closely related procedures and consideration of other available information, we determined that 16 of the procedures would predominantly be performed in physicians' offices. However, because we had no utilization data for the procedures specifically described by these new HCPCS codes, we made the office-based designations temporary rather than permanent and stated that we would reevaluate the procedures when data become available (74 FR 60607 through 60608). The temporary payment indicators for the 16 office-based procedures displayed in Table 47 were interim designations and were open to public comment during the 60-day comment period following the release of the CY 2010 OPPS/ASC final rule with comment period. We will respond to public comments received during that 60-day comment period as well as the comment period following this proposed rule in the CY 2011 OPPS/ASC final rule with comment period.

TABLE 47.—PROPOSED CY 2011 PAYMENT INDICATORS FOR NEW CY 2010 HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED ON AN INTERIM BASIS IN THE CY 2010 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

CY 2010 HCPCS Code	CY 2010 Long Descriptor	CY 2010 ASC Payment Indicator	Proposed CY 2011 ASC Payment Indicator**
21015	Radical resection of tumor (eg, malignant neoplasm), soft tissue of face or scalp; less than 2 cm	R2 *	R2**
21555	Excision, tumor, soft tissue of neck or anterior thorax, subcutaneous; less than 3 cm	P3*	P3**

CY 2010 HCPCS Code	CY 2010 Long Descriptor	CY 2010 ASC Payment Indicator	Proposed CY 2011 ASC Payment Indicator**
21930	Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm	P3*	P3**
23075	Excision, tumor, soft tissue of shoulder area, subcutaneous; less than 3 cm	P3*	P3**
24075	Excision, tumor, soft tissue of upper arm or elbow area, subcutaneous; less than 3 cm	P3*	P3**
25075	Excision, tumor, soft tissue of forearm and/or wrist area, subcutaneous; less than 3 cm	P3*	P3**
26115	Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; less than 1.5 cm	P3*	P3**
27047	Excision, tumor, soft tissue of pelvis and hip area, subcutaneous; less than 3 cm	P3*	P3**
27327	Excision, tumor, soft tissue of thigh or knee area, subcutaneous; less than 3 cm	P3*	P3**
27618	Excision, tumor, soft tissue of leg or ankle area, subcutaneous; less than 3 cm	P3*	P3**
28039	Excision, tumor, soft tissue of foot or toe, subcutaneous; 1.5 cm or greater	P3*	P3**
28041	Excision, tumor, soft tissue of foot or toe, subfascial (eg, intramuscular); 1.5 cm or greater	R2*	R2**
28043	Excision, tumor, soft tissue of foot or toe, subcutaneous; less than 1.5 cm	P3*	P3**
28045	Excision, tumor, soft tissue of foot or toe, subfascial (eg, intramuscular); less than 1.5 cm	P3*	P3**
28046	Radical resection of tumor (eg, malignant neoplasm), soft tissue of foot or toe; less than 3 cm	R2*	R2**
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg	R2*	R2**

* If designation is temporary.

**Proposed payment indicators are based on a comparison of the proposed rates according to the ASC standard rate setting 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 2011. Therefore, this proposed rule reflects a negative update to the MPFS payment rates for CY 2011. If Congress revises the MPFS update for CY 2011, we will recalculate the ASC payment rates using the revised update factor in the CY 2011 OPPS/ASC final rule with comment period.

c. ASC Covered Surgical Procedures Designated as Device-Intensive

(1) Background

As discussed in the August 2, 2007 final rule (72 FR 42503 through 42508), we adopted a modified payment methodology for calculating the ASC payment rates for covered surgical procedures that are assigned to the subset of OPPS device-dependent APCs with a device offset percentage greater than 50 percent of the APC cost under the OPPS, in order to ensure that payment for the procedure is adequate to provide packaged payment for the high-cost implantable devices used in those procedures. 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). The device-intensive procedures for which the modified rate calculation methodology applies in CY 2010 were displayed in Table 68 and in Addendum AA to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60610 through 60611 and 60692 through 60752).

(2) Proposed Changes to List of Covered Surgical Procedures Designated as Device Intensive for CY 2011

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 2011, 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 2009 OPPS claims and cost report data available for the proposed rule. The OPPS device-dependent APCs are discussed further in section II.A.2.d.(1) of this proposed rule. The ASC covered surgical procedures that we are proposing to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology for CY 2011 are listed in Table 48 below. The CPT code, the CPT code short descriptor, the proposed CY 2011 ASC payment indicator, the proposed CY 2011 OPPS APC assignment and title, and the proposed CY 2011 OPPS APC device offset percentage are also listed in Table 48 below. Each proposed device-intensive procedure is assigned payment indicator "H8" or "J8" depending on whether it was subject to transitional payment prior to CY 2011, and all of these procedures are included in Addendum AA to this proposed rule.

TABLE 48.--ASC COVERED SURGICAL PROCEDURES PROPOSED FOR DEVICE-INTENSIVE DESIGNATION FOR CY 2011

CY 2010 CPT Code	CY 2010 Short Descriptor	Proposed CY 2011 ASC Payment Indicator	Proposed CY 2011 OPPS APC	OPPS APC Title	Proposed CY 2011 Device-Dependent APC Offset Percentage
24361	Reconstruct elbow joint	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%
24363	Replace elbow joint	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%
24366	Reconstruct head of radius	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%
25441	Reconstruct wrist joint	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%
25442	Reconstruct wrist joint	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%
25446	Wrist replacement	H8	0425	Level II Arthroplasty or	59%

CY 2010 CPT Code	CY 2010 Short Descriptor	Proposed CY 2011 ASC Payment Indicator	Proposed CY 2011 OPPS APC	OPPS APC Title	Proposed CY 2011 Device-Dependent APC Offset Percentage
				Implantation with Prosthesis	
27446	Revision of knee joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%
33206	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	70%
33207	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	70%
33208	Insertion of heart pacemaker	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	73%
33212	Insertion of pulse generator	H8	0090	Insertion/Replacement of Pacemaker Pulse Generator	72%
33213	Insertion of pulse generator	H8	0654	Insertion/Replacement of a permanent dual chamber pacemaker	73%
33214	Upgrade of pacemaker system	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	73%
33224	Insert pacing lead & connect	J8	0418	Insertion of Left Ventricular Pacing Elect.	72%
33225	Lventric pacing lead add-on	J8	0418	Insertion of Left Ventricular Pacing Elect.	72%
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	71%
53440	Male sling procedure	H8	0385	Level I Prosthetic Urological Procedures	61%
53444	Insert tandem cuff	H8	0385	Level I Prosthetic Urological Procedures	61%
53445	Insert uro/ves nck sphincter	H8	0386	Level II Prosthetic Urological Procedures	71%
53447	Remove/replace ur sphincter	H8	0386	Level II Prosthetic Urological Procedures	71%
54400	Insert semi-rigid prosthesis	H8	0385	Level I Prosthetic Urological Procedures	61%

CY 2010 CPT Code	CY 2010 Short Descriptor	Proposed CY 2011 ASC Payment Indicator	Proposed CY 2011 OPPS APC	OPPS APC Title	Proposed CY 2011 Device-Dependent APC Offset Percentage
54401	Insert self-contd prosthesis	H8	0386	Level II Prosthetic Urological Procedures	71%
54405	Insert multi-comp penis pros	H8	0386	Level II Prosthetic Urological Procedures	71%
54410	Remove/replace penis prosth	H8	0386	Level II Prosthetic Urological Procedures	71%
54416	Remv/repl penis contain pros	H8	0386	Level II Prosthetic Urological Procedures	71%
55873	Cryoablate prostate	H8	0674	Prostate Cryoablation	58%
61885	Insrt/redo neurostim 1 array	H8	0039	Level I Implantation of Neurostimulator Generator	85%
61886	Implant neurostim arrays	H8	0315	Level II Implantation of Neurostimulator Generator	88%
62361	Implant spine infusion pump	H8	0227	Implantation of Drug Infusion Device	81%
62362	Implant spine infusion pump	H8	0227	Implantation of Drug Infusion Device	81%
63650	Implant neuroelectrodes	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes	56%
63655	Implant neuroelectrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	63%
63685	Insrt/redo spine n generator	H8	0039	Level I Implantation of Neurostimulator Generator	85%
64553	Implant neuroelectrodes	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes	56%
64555	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes	56%
64560	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes	56%
64561	Implant neuroelectrodes	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes	56%
64565	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes	56%
64573	Implant neuroelectrodes	H8	0225	Implantation of Neurostimulator Electrodes, Cranial Nerve	78%
64575	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	63%

CY 2010 CPT Code	CY 2010 Short Descriptor	Proposed CY 2011 ASC Payment Indicator	Proposed CY 2011 OPPS APC	OPPS APC Title	Proposed CY 2011 Device-Dependent APC Offset Percentage
64577	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	63%
64580	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	63%
64581	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	63%
64590	Insrt/redo pn/gastr stimul	H8	0039	Level I Implantation of Neurostimulator Generator	85%
65770	Revise cornea with implant	H8	0293	Level VI Anterior Segment Eye Procedures	59%
69714	Implant temple bone w/stimul	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%
69715	Temple bne implnt w/stimulat	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%
69717	Temple bone implant revision	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%
69718	Revise temple bone implant	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%
69930	Implant cochlear device	H8	0259	Level VII ENT Procedures	86%

d. ASC Treatment of Surgical Procedures Proposed for Removal from the OPPS Inpatient List for CY 2011

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 procedures 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 2011 according to the criteria for exclusion from the list of covered ASC surgical procedures. We believe that all of these procedures should continue to be excluded from the ASC list of covered surgical

procedures for CY 2011 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 2011 and the procedures we are proposing to remove from the OPPS inpatient list for CY 2011 may be found in section XI.B. of this proposed rule. The HCPCS codes for these three procedures and their long descriptors are listed in Table 49 below.

TABLE 49.—PROCEDURES PROPOSED FOR EXCLUSION FROM THE ASC LIST OF COVERED PROCEDURES FOR CY 2011 THAT ARE PROPOSED FOR REMOVAL FROM THE CY 2011 OPPS INPATIENT LIST

CY 2010 HCPCS Code	CY 2010 Long Descriptor
21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)
25909	Amputation, forearm, through radius and ulna; re-amputation

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 2011 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 2011. For example, a covered ancillary service that was separately paid under the revised ASC payment system in CY 2010 may be proposed for packaged status under the CY 2011 OPPS and, therefore, also under the ASC payment system for CY 2011. Comment indicator "CH," discussed in section XV.F. of this proposed rule, is used in Addendum

BB to this proposed rule 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 2011.

Except for the Level II HCPCS codes listed in Table 41 of this proposed rule, all ASC covered ancillary services and their proposed payment indicators for CY 2011 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 indicators "H8" and "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 2010 OPPS/ASC final rule with comment period (74 FR 60596 through 60629), we updated the CY 2009 ASC payment rates for ASC covered surgical procedures with payment indicators of "A2," "G2," "H8," and "J8" using CY 2008 data, consistent with the CY 2010 OPPS update. Payment rates for device-intensive procedures also were updated to incorporate the CY 2010 OPPS device offset percentages.

Payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") are the lower of the MPFS non-facility PE RVU amount (we refer readers to the CY 2011 MPFS proposed rule) or the amount calculated using the ASC standard ratesetting methodology for the procedure. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60596 through 60629), 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 2010 rate for each of the office-based procedures, calculated according to the ASC standard ratesetting methodology, to the MPFS nonfacility PE RVU amount (multiplied by the conversion factor) to determine which was lower and, therefore, would be the CY 2010 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 2011

We are proposing to update ASC payment rates for CY 2011 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 2011 payments for procedures formerly subject to the transitional payment methodology (payment indicators "A2" and "H8") using the proposed CY 2011 ASC rate calculated according to the ASC standard ratesetting methodology, incorporating the device-intensive procedure methodology, as appropriate, for procedures assigned ASC payment indicator "H8." We are not proposing to modify the payment indicators for procedures that were subject to transitional payment prior to CY 2011 but will consider doing so in future rulemaking. 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 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 2011 OPPS proposal that reflects updated OPPS device offset percentages, and to make payment for office-based procedures at the lesser of the CY 2011 proposed MPFS non-facility PE RVU amount or the proposed CY 2011 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 2011 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 2011. Table 50 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 2011. Specifically, when a procedure that is listed in Table 50 is performed to implant a device that is listed in Table 51 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 50 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 50 when the facility receives a partial credit of 50 percent or more of the cost of a device listed in Table 51 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 50.—PROPOSED CY 2011 PROCEDURES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY WOULD APPLY

CY 2010 CPT Code	CY 2010 Short Descriptor	Proposed CY 2011 ASC Payment Indicator	Proposed CY 2011 OPPS APC	OPPS APC Title	Proposed CY 2011 OPPS Full APC Offset Percentage	Proposed CY 2011 OPPS Partial APC Offset Percentage
24361	Reconstruct elbow joint	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
24363	Replace elbow joint	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
24366	Reconstruct head of radius	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
25441	Reconstruct wrist joint	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
25442	Reconstruct wrist joint	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
25446	Wrist replacement	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
27446	Revision of knee joint	J8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
33206	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	70%	35%
33207	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	70%	35%
33208	Insertion of heart pacemaker	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	73%	37%
33212	Insertion of pulse generator	H8	0090	Insertion/Replacement of Pacemaker Pulse Generator	72%	36%
33213	Insertion of pulse generator	H8	0654	Insertion/Replacement of a permanent dual chamber pacemaker	73%	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	0418	Insertion of Left Ventricular Pacing Elect.	72%	36%
33225	Lventric pacing lead add-on	J8	0418	Insertion of Left Ventricular Pacing Elect.	72%	36%
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%	44%

CY 2010 CPT Code	CY 2010 Short Descriptor	Proposed CY 2011 ASC Payment Indicator	Proposed CY 2011 OPPS APC	OPPS APC Title	Proposed CY 2011 OPPS Full APC Offset Percentage	Proposed CY 2011 OPPS Partial APC Offset Percentage
33282	Implant pat-active ht record	J8	0680	Insertion of Patient Activated Event Recorders	71%	35%
53440	Male sling procedure	H8	0385	Level I Prosthetic Urological Procedures	61%	30%
53444	Insert tandem cuff	H8	0385	Level I Prosthetic Urological Procedures	61%	30%
53445	Insert uro/ves nck sphincter	H8	0386	Level II Prosthetic Urological Procedures	71%	36%
53447	Remove/replace ur sphincter	H8	0386	Level II Prosthetic Urological Procedures	71%	36%
54400	Insert semi-rigid prosthesis	H8	0385	Level I Prosthetic Urological Procedures	61%	30%
54401	Insert self-contd prosthesis	H8	0386	Level II Prosthetic Urological Procedures	71%	36%
54405	Insert multi-comp penis pros	H8	0386	Level II Prosthetic Urological Procedures	71%	36%
54410	Remove/replace penis prosth	H8	0386	Level II Prosthetic Urological Procedures	71%	36%
54416	Remv/repl penis contain pros	H8	0386	Level II Prosthetic Urological Procedures	71%	36%
61885	Insrt/redo neurostim 1 array	H8	0039	Level I Implantation of Neurostimulator Generator	85%	43%
61886	Implant neurostim arrays	H8	0315	Level II Implantation of Neurostimulator Generator	88%	44%
62361	Implant spine infusion pump	H8	0227	Implantation of Drug Infusion Device	81%	41%
62362	Implant spine infusion pump	H8	0227	Implantation of Drug Infusion Device	81%	41%
63650	Implant neuroelectrodes	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes	56%	28%
63655	Implant neuroelectrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	63%	31%
63685	Insrt/redo spine n generator	H8	0039	Level I Implantation of Neurostimulator Generator	85%	43%
64553	Implant neuroelectrodes	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes	56%	28%
64555	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes	56%	28%

CY 2010 CPT Code	CY 2010 Short Descriptor	Proposed CY 2011 ASC Payment Indicator	Proposed CY 2011 OPPS APC	OPPS APC Title	Proposed CY 2011 OPPS Full APC Offset Percentage	Proposed CY 2011 OPPS Partial APC Offset Percentage
64560	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes	56%	28%
64561	Implant neuroelectrodes	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes	56%	28%
64565	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes	56%	28%
64573	Implant neuroelectrodes	H8	0225	Implantation of Neurostimulator Electrodes, Cranial Nerve	78%	39%
64575	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	63%	31%
64577	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	63%	31%
64580	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	63%	31%
64581	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	63%	31%
64590	Insrt/redo pn/gastr stimul	H8	0039	Level I Implantation of Neurostimulator Generator	85%	43%
69714	Implant temple bone w/stimul	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
69715	Temple bne implnt w/stimulat	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
69717	Temple bone implant revision	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
69718	Revise temple bone implant	H8	0425	Level II Arthroplasty or Implantation with Prosthesis	59%	29%
69930	Implant cochlear device	H8	0259	Level VII ENT Procedures	86%	43%

TABLE 51.— PROPOSED DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE IN CY 2011 WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT

CY 2010 Device HCPCS Code	CY 2010 Short Descriptor
C1721	AICD, dual chamber
C1722	AICD, single chamber
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
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
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
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

d. Proposed Waiver of Coinsurance and Deductible for Certain Preventive Services

As discussed in detail in section XII.B. of this proposed rule and in the CY 2011 MPFS proposed rule, sections 4104(b) and 10406 of the Affordable Care Act amended section 1833(a)(1) of the Act, in pertinent part, to waive the coinsurance for those preventive services described in section 1861(ww)(2) of the Act (excluding electrocardiograms) that are recommended by the 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 these preventive services. These provisions apply to these items and services furnished in ASCs on or after January 1, 2011. In section XII.B. of this proposed rule and in the CY 2011 MPFS proposed rule, we are proposing to define the preventive services to which this provision applies and to apply the criteria specified in section 4104 of the Affordable Care Act for the waiver of coinsurance and deductible.

Table 52 identifies the ASC covered surgical and ancillary services that are included in the proposed definition of preventive services in section XII.B. of this proposed rule and in the CY 2011 MPFS proposed rule. All of the ASC covered surgical and ancillary services that are included in the chart below are preventive services that are recommended by the USPSTF with a grade of A or B. Therefore, we are proposing to update §416.160(a)(4) and add new §416.160(a)(5) on the scope and basis of the ASC regulations and to update §410.152(l) in this proposed rule to reflect the waiver of coinsurance and deductible for these services. We refer readers to the CY 2011 MPFS proposed rule for a discussion of the proposed changes to §410.160(b) and proposed

additional changes to §410.152 of our regulations to implement the provisions related to the definition of preventive services and the waiver of the coinsurance and deductible for preventive services as specified by sections 4103, 4104, and 10406 of the Affordable Care Act.

TABLE 52.--PROPOSED CY 2011 ASC PREVENTIVE SERVICES FOR WHICH COINSURANCE AND DEDUCTIBLE WOULD BE WAIVED IN CY 2011

Service	CY 2010 CPT/ HCPCS Code	CY 2010 Long Descriptor	CY 2011 Coins. / Deductible	Proposed CY 2011 ASC Payment Indicator
Bone Mass Measurement	G0130	Single energy x-ray absorptiometry (sexa) bone density study, one or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)	Waived	Z3
	77078	Computed tomography, bone mineral density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)	Waived	Z2
	77079	Computed tomography, bone mineral density study, 1 or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)	Waived	Z3
	77080	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)	Waived	Z2
	77081	Dual-energy x-ray absorptiometry (dxa), bone density study, 1 or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)	Waived	Z3
	77083	Radiographic ~~absorptiometry (eg,~~ photodensitometry,	Waived	Z3

Service	CY 2010 CPT/ HCPCS Code	CY 2010 Long Descriptor	CY 2011 Coins. / Deductible	Proposed CY 2011 ASC Payment Indicator
		radiogrammetry), 1 or more sites		
	76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method	Waived	Z3
Colorectal Cancer Screening	G0104	Colorectal cancer screening; flexible sigmoidoscopy	Waived	P3
	G0105	Colorectal cancer screening; colonoscopy on individual at high risk	Waived	A2
	G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk	Waived	A2
Influenza Virus Vaccine	90655	Influenza virus vaccine, split virus, preservative free, when administered to children 6-35 months of age, for intramuscular use	Waived	L1
	90656	Influenza virus vaccine, split virus, preservative free, when administered to individuals 3 years and older, for intramuscular use	Waived	L1
	90657	Influenza virus vaccine, split virus, when administered to children 6-35 months of age, for intramuscular use	Waived	L1
	90658	Influenza virus vaccine, split virus, when administered to individuals 3 years of age and older, for intramuscular use	Waived	L1
	90660	Influenza virus vaccine, live, for intranasal use	Waived	L1
	90662	Influenza virus vaccine, split virus, preservative free, enhanced immunogenicity via increased antigen content, for intramuscular use	Waived	L1

Service	CY 2010 CPT/ HCPCS Code	CY 2010 Long Descriptor	CY 2011 Coins. / Deductible	Proposed CY 2011 ASC Payment Indicator
	G9141	Influenza a (h1n1) immunization administration (includes the physician counseling the patient/family)	Waived	L1
	G9142	Influenza a (h1n1) vaccine, any route of administration	Waived	L1
Pneumococcal Vaccine	90669	Pneumococcal conjugate vaccine, polyvalent, when administered to children younger than 5 years, for intramuscular use	Waived	L1
	90670	Pneumococcal conjugate vaccine, 13 valent, for intramuscular use	Waived	L1
	90732	Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, when administered to individuals 2 years or older, for subcutaneous or intramuscular use	Waived	L1
Hepatitis B Vaccine	90740	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (3 dose schedule), for intramuscular use	Waived	F4
	90743	Hepatitis B vaccine, adolescent (2 dose schedule), for intramuscular use	Waived	F4
	90744	Hepatitis B vaccine, pediatric/adolescent dosage (3 dose schedule), for intramuscular use	Waived	F4
	90746	Hepatitis B vaccine, adult dosage, for intramuscular use	Waived	F4

Service	CY 2010 CPT/ HCPCS Code	CY 2010 Long Descriptor	CY 2011 Coins. / Deductible	Proposed CY 2011 ASC Payment Indicator
	90747	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (4 dose schedule), for intramuscular use	Waived	F4

Section 4104(c) of the Affordable Care Act amended section 1833(b) of the Act to waive the Part B deductible for colorectal cancer screening tests that become diagnostic. Specifically, section 4104(c)(2) of the Affordable Care Act waives the deductible with respect to a colorectal cancer screening test "regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test." As discussed in section XII.B. of this proposed rule and in the CY 2011 MPFS proposed rule, we are proposing that all surgical services furnished on the same date as a planned screening colonoscopy or planned flexible sigmoidoscopy would be considered as being "furnished in connection with, as a result of, and in the same clinical encounter as the screening test." We believe that this interpretation is appropriate because we believe that it would be very rare for an unrelated surgery to occur on the same date as one of these scheduled screening tests. Moreover, we believe that the risk of improper expenditures would be very small under this policy because it is the deductible, and not the coinsurance, that is waived for the related procedures other than the screening tests. In the event of a legislative change to this policy (for example, a statutory change that would waive the coinsurance for these

related services in addition to the deductible), we would reassess the appropriateness of this proposed definition of services that are furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test that becomes diagnostic. We also note that the annual deductible would likely be met when any surgical procedure (related or not) is performed on the same day as the scheduled screening test.

We are proposing to implement this provision by creating a HCPCS modifier that ASCs would append to the diagnostic procedure code that is reported instead of the screening colonoscopy or screening flexible sigmoidoscopy HCPCS code. The claims processing system would respond to the modifier by waiving the deductible for all surgical services on the same date as the diagnostic test. Coinsurance or copayment would continue to apply to the diagnostic test and to other services furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

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).

Our ASC payment policies provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates, while we pay for separately payable radiology services at the lower of the MPFS non-facility PE RVU (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). In all cases, ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare, in order for those ancillary services also to be paid.

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. Subsequent to 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. As discussed in section IV.A.1. of this proposed rule, new pass-through device categories may be established on a quarterly basis, but currently there are no OPPS device pass-through categories that would continue for OPPS pass-through payment (and, correspondingly, separate ASC payment) in CY 2011.

b. Proposed Payment for Covered Ancillary Services for CY 2011

For CY 2011, 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 2011 OPPS and ASC payment rates. The proposed CY 2011 OPPS payment methodologies for separately payable drugs and biologicals and

brachytherapy sources are discussed in sections V. and VII. of this proposed rule, respectively, and we are proposing to set the CY 2011 ASC payment rates for those services equal to the proposed CY 2011 OPPS rates.

Consistent with established ASC payment policy (72 FR 42497), the proposed CY 2011 payment for separately payable covered radiology services is based on a comparison of the CY 2011 proposed MPFS non-facility PE RVU amounts (we refer readers to the CY 2011 MPFS proposed rule) and the proposed CY 2011 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 indicate whether the proposed payment rates for radiology services are based on the MPFS nonfacility PE RVU amount or the ASC standard rate setting 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 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).

All covered ancillary services and their proposed payment indicators are listed in Addendum BB to this proposed rule.

E. New Technology Intraocular Lenses (NTIOLs)

1. Background

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 active 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 a NTIOL class that is qualified for a payment adjustment. Specifically, we established the following process:

- We announce annually in the **Federal Register** a document that proposes the update of ASC 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 **Federal Register** document that finalizes the update of ASC payment rates for the following calendar year, we--

  ° Provide a list of determinations made as a result of our review of all new 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 determining whether a lens belongs to a new class of NTIOLs and whether the ASC payment amount for insertion of that lens in conjunction with cataract surgery is appropriate, we expect that the insertion of the candidate IOL would result in significantly improved clinical outcomes compared to currently available IOLs. In addition, to establish a new NTIOL class, the candidate lens must be distinguishable from lenses already approved as members of active or expired classes of NTIOLs that share a predominant characteristic associated with improved clinical outcomes that was identified for each class. Furthermore, 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 factors set out at §416.195:

- 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 IOL is not 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; and

- Evidence demonstrates that use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs.

According to the statute, and consistent with previous examples provided by CMS, superior outcomes that we consider include the following:

- ° Reduced risk of intraoperative or postoperative complication or trauma;
- ° Accelerated postoperative recovery;
- ° Reduced induced astigmatism;
- ° Improved postoperative visual acuity;
- ° More stable postoperative vision; and/or
- ° Other comparable clinical advantages, such as--
  - ▫ Reduced dependence on other eyewear (for example, spectacles, contact lenses, and reading glasses);
  - ▫ Decreased rate of subsequent diagnostic or therapeutic interventions, such as the need for YAG laser treatment;
  - ▫ Decreased incidence of subsequent IOL exchange; and
  - ▫ Decreased blurred vision, glare, other quantifiable symptom or vision deficiency.

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

As we stated in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68180), there are three possible outcomes from our review of a request for

establishment of a new NTIOL class. As appropriate, for each completed request for consideration of a candidate IOL into a new class that is received by the established deadline, one of the following determinations is announced annually in the final rule updating the ASC payment rates for the next calendar year:

- The request for a payment adjustment is approved for the candidate IOL for 5 full years as a member of a new NTIOL class described by a new HCPCS code;
- The request for a payment adjustment is approved for the candidate IOL for the balance of time remaining as a member of an active NTIOL class; or
- The request for a payment adjustment is not approved.

We also discussed our plan to summarize briefly in the final rule with comment period the evidence that we reviewed, the public comments, and the basis for our determinations in consideration of applications for establishment of a new NTIOL class. We established that 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 improved clinical outcomes. 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.

2. NTIOL Application Process for Payment Adjustment

In CY 2007, we posted an updated guidance document to the CMS Web site to provide process and information requirements for applications requesting a review of the

appropriateness of the payment amount for insertion of an IOL to ensure that the ASC payment for covered surgical procedures includes payment that is reasonable and related to the cost of acquiring a lens that is approved as belonging to a new class of NTIOLs. This guidance document can be accessed on the CMS Web site at: http://www.cms.gov/ASCPayment/downloads/NTIOLprocess.pdf.

We note that we have also issued a guidance document entitled "Revised Process for Recognizing Intraocular Lenses Furnished by Ambulatory Surgery Centers (ASCs) as Belonging to an Active Subset of New Technology Intraocular Lenses (NTIOLs)." This guidance document can be accessed on the CMS Web site at: http://www.cms.gov/ASCPayment/Downloads/Request_for_inclusion_in_current_NTIOL_subset.pdf.

This second guidance document provides specific details regarding requests for recognition of IOLs as belonging to an existing, active NTIOL class, the review process, and information required for a request to review. Currently, there is one active NTIOL class whose defining characteristic is the reduction of spherical aberration. We accept requests throughout the year to review the appropriateness of recognizing an IOL as a member of an active class of NTIOLs. That is, review of candidate lenses for membership in an existing, active NTIOL class is ongoing and not limited to the annual review process that applies to the establishment of new NTIOL classes. We ordinarily complete the review of such a request within 90 days of receipt of all information that we consider pertinent to our review, and upon completion of our review, we notify the requestor of our determination and post on the CMS Web site notification of a lens newly

approved for a payment adjustment as an NTIOL belonging to an active NTIOL class when furnished in an ASC.

3. Classes of NTIOLs Approved and New Requests for Payment Adjustment

a. Background

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 following table, with the associated qualifying IOLs to date:

NTIOL Class	HCPCS Code	$50 Approved for Services Furnished On or After	NTIOL Characteristic	IOLs Eligible for Adjustment
1	Q1001	May 18, 2000, through May 18, 2005	Multifocal	Allergan AMO Array Multifocal lens, model SA40N
2	Q1002	May 18, 2000, through May 18, 2005	Reduction in Preexisting Astigmatism	STAAR Surgical Elastic Ultraviolet-Absorbing Silicone Posterior Chamber IOL with Toric Optic, models AA4203T, AA4203TF, and AA4203TL

NTIOL Class	HCPCS Code	$50 Approved for Services Furnished On or After	NTIOL Characteristic	IOLs Eligible for Adjustment
3	Q1003	February 27, 2006, through February 26, 2011	Reduced Spherical Aberration	Advanced Medical Optics (AMO) Tecnis® IOL models Z9000, Z9001, Z9002, ZA9003, and AR40xEM and Tecnis® 1-Piece model ZCB00; Alcon Acrysof® IQ Model SN60WF, Acrysert Delivery System model SN60WS and Acrysof ® IQ Toric model SN6ATT; Bausch & Lomb Sofport AO models LI61AO and LI61AOV and Akreos AO models AO60 and MI60, Crystalens® AT-50AO and AT-52AO; STAAR Affinity Collamer model CQ2015A and CC4204A and Elastimide model AQ2015A; Hoya model FY-60AD, FC-60AD, PY-60AD, and PC-60AD

b. Request to Establish New NTIOL Class for CY 2010 and Deadline for Public Comment

As explained in the guidance document on the CMS Web site, the deadline for each year's requests for review of the appropriateness of the ASC payment amount for insertion of a candidate IOL as a member of a new class of NTIOLs is announced in the final rule updating the ASC and OPPS payment rates for that calendar year. Therefore, a request for review for a new class of NTIOLs for CY 2011 must have been submitted to CMS by March 8, 2010, the due date published in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60621). We received one request for review to establish a

new NTIOL class for CY 2011 by the March 8, 2010 due date. A summary of this request follows.

Requestor/Manufacturer: Alcon Laboratories, Inc.

Lens Model Number: Acrysof®Natural IOLs, Models: SN60WF, SN60AT, MN60MA, and MN60AC.

Summary of the Request: Alcon Laboratories, Inc. (Alcon) submitted a request for CMS to determine that its Acrysof® Natural intraocular lenses meet the criteria for recognition as NTIOL and to concurrently establish a new class of NTIOLs for blue light filtering to improve driving safety under glare conditions, with these lenses as members. As part of its request, Alcon submitted descriptive information about the candidate IOLs as outlined in the guidance document that we make 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 U.S Food and Drug Administration (FDA). This information included the approved labeling for the candidate lenses, a summary of the IOLs' safety and effectiveness, a copy of the FDA's approval notification, and instructions for their use. In addition, Alcon also submitted a number of studies in support of its claim that the blue light filtering design features of the candidate lenses would improve driving safety under glare conditions. We note that we have previously considered another candidate IOL for which ASC payment review was requested on the basis of blue light filtering properties. We discussed these lenses in the July 23, 2004 and March 25, 2005 NTIOL proposed and final rules published in the **Federal Register** (69 FR 44029 and 70 FR 15337, respectively).

In its CY 2011 request, Alcon asserts that its request is based on new research and measurement technologies that demonstrate that the Acrysof® Natural IOLs with a blue light filtering chromophore filters 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 its IOL.

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 that are outlined in the discussion 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 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. We note that FDA approval for the candidate lens was granted in May 2007 and that Alcon provided FDA approval documentation, including a copy of the FDA's approval

notification, the FDA's summary of the IOL's safety and effectiveness, and the labeling approved by the FDA in its request for a new class of NTIOLs. The approved labels for the Alcon IOLs all state, "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 label does not otherwise reference specific clinical benefits or lens characteristics of blue light filtering on glare. We are interested in public comments on the specific clinical benefits or lens characteristics with established clinical relevance for the blue light filter effects on glare. Specifically, we are interested in public comments regarding the assertion that the specific blue light filter properties associated with the candidate IOLs improve driving safety via the reduction of glare.

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. As noted in the table above regarding active and expired NTIOL classes, since implementation of the NTIOL review process 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 currently active Reduced Spherical Aberration class, which was created in 2006 and will expire in 2011. The class-defining characteristic specific to IOLs that are members of these 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. We refer readers to the table above for information about the NTIOL classes that have been created since the implementation of the review process. Based on this information, the candidate lens may not be described by an active or expired NTIOL class. Its proposed class-defining characteristic and associated clinical benefits that were described in the submitted request, specifically the blue light filtering properties, may not be similar to the class-defining characteristics and associated benefits of the two expired NTIOL classes, the Multifocal and Reduction in Preexisting Astigmatism classes, or to the class-defining characteristic and associated benefits of the currently active Reduced Spherical Aberration class. We welcome public comments that address whether the proposed class-defining characteristic and associated clinical benefits of the candidate Alcon IOLs are described by the expired or currently active 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 use of 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. For purposes of reviewing this request to establish a new NTIOL class for CY 2011, we believe that foldable, spherical, monofocal IOLs made of acrylic, silicone, or polymethylmethacrylate materials

represent the currently available lenses against which the candidate NTIOL to establish a new class should be compared. The Alcon request asserts that the proprietary blue light filtering chromophore incorporated into the design of the candidate lenses and asserted associated benefits makes them different from IOLs that are currently available in the U.S. market. We are again seeking public comment on our view of "currently available lenses" for the purposes of this CY 2011 review.

We reviewed the evidence submitted as part of the request, including two peer-reviewed articles and two related clinical studies. The first of the submitted articles discussed the effect of the candidate lenses on glare disability, while the second article discussed the effects of glare on driving in simulated driving conditions. The requestor also submitted data from two clinical studies directly related to the submitted articles discussed above. One cross sectional study with a planned sample size of 70 subjects evaluated glare disability by comparing the candidate lenses against control lenses which did not include the blue light filtering chromophore. Results from this study suggest that subjects implanted with the applicant IOLs had significantly faster photostress recovery times than subjects who had control IOLs implanted without the blue light filtering chromophore. We note that this cross sectional study is ongoing; consequently the preliminary results submitted with the request only reflect 40 subjects from the planned total sample size. The requestor also submitted data from a second clinical study with a total sample size of 34 that evaluated the benefit of the blue light filtering chromophore on driving performance in patients implanted with the candidate IOLs compared to patients implanted with non blue light filtering IOLs. The results from this study

suggested that incorporation of the yellow chromophore into the design of the candidate lenses reduce glare disability and thereby improve the ability of older drivers implanted with the candidate lenses to drive safely. 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 optic. Specifically, we are seeking public comment and relevant data on the following:

- Are there other peer-reviewed data that would support or disprove the claims of clinical benefit made by the applicant?
- The presented studies compare the blue filtering optic to clear IOLs, are there other IOLs or other clinical alternatives for reducing glare?
- Is the sample size used in both studies sufficient considering all confounding variables including, but not limited to age, sex, race, time from surgery, status of eyes (which eye received the IOL or both eyes, for example) to conclude that a blue light filtering optic would reduce glare 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 clarify that the blue filtering optic is responsible for reduction in glare disability as asserted by applicant?

We welcome public comments and relevant data specifically addressing whether use of the Alcon Acrysof® Natural IOLs result in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. Additionally, in accordance with our established NTIOL review process, we are 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. All comments on this request must be received by [insert date 30 days after date of publication]. The announcement of CMS' determination regarding this request will appear in the CY 2011 OPPS/ASC final rule with comment period. If a determination of membership of the candidate lens in a new or currently active 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 5-year period from the implementation date of a new NTIOL class is $50. In the CY 2007 OPPS/ASC final rule with comment period, we revised §416.200(a) through (c) to clarify how the IOL payment adjustment is made and how an NTIOL is paid after expiration of the payment adjustment, and made minor editorial changes to §416.200(d). For CY 2008, CY 2009, and CY 2010, we did not revise the payment adjustment amount, and we are not proposing to revise the payment adjustment amount for CY 2011 in light of our limited experience with the revised ASC payment system, implemented initially on January 1, 2008.

5. Proposed ASC Payment for Insertion of IOLs

In accordance with the final policies of the revised ASC payment system, for CY 2011, payment for IOL insertion procedures is established according to the standard payment methodology of the revised payment system, which multiplies the ASC conversion factor by the ASC payment weight for the surgical procedure to implant the IOL. CY 2011 ASC payment for the cost of a conventional lens is packaged into the payment for the associated covered surgical procedures performed by the ASC. The HCPCS codes for IOL insertion procedures were included in Table 53 below, and their proposed CY 2011 payment rates may be found in Addendum AA to this proposed rule.

TABLE 53.--INSERTION OF IOL PROCEDURES

CY 2010 HCPCS Code	CY 2010 Long Descriptor
66983	Intracapsular cataract extraction with insertion of intraocular lens prosthesis (one stage procedure)
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification)
66985	Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract removal
66986	Exchange of intraocular lens

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). We will respond to public comments and finalize the ASC treatment of all codes labeled with comment indicator "NI" in the CY 2011 OPPS/ASC final rule with comment period.

The “CH” comment indicator is used in Addenda AA and BB to this CY 2011 proposed rule to indicate that a new payment indicator (in comparison with the indicator for the CY 2010 ASC April quarterly update) 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 payment indicators and comment indicators are provided in Addenda DD1 and DD2 to this proposed rule.

2. Proposed ASC Payment and Comment Indicators

We are not proposing any changes to the definitions of the ASC payment and comment indicators for CY 2011. We will consider proposing to modify the payment indicators for procedures that were subject to transitional payment prior to CY 2011 in future rulemaking. We refer readers to Addenda DD1 and DD2 to this proposed rule for the complete list.

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), (C), and (D) of sections 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. The following section describes a recent MedPAC recommendation that is relevant to the ASC payment system.

The March 2010 MedPAC "Report to the Congress: Medicare Payment Policy" included the following recommendation relating specifically to the ASC payment system for CY 2011:

Recommendation 2C: The Congress should implement a 0.6 percent increase in payment rates for ambulatory surgical center services in calendar year 2011 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 2C 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 stated 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). We responded that we would keep the commenters' perspectives in mind as we further consider the adequacy of the Medicare ASC payment rates and move toward implementation of ASC quality reporting.

Consistent with our CY 2010 policy, we are proposing not to require ASCs to submit cost data to the Secretary for CY 2011. We continue to believe that our established methodology results in appropriate payment rates for ASCs. As noted in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60623), 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 restate our belief that promoting high quality care in

the ASC setting through quality reporting is highly desirable and fully in line with our efforts under other payment systems. As discussed in section XVI.H. of this proposed rule, we are proposing not to require ASC quality data reporting for CY 2011, but our intention is to implement ASC quality reporting in a future rulemaking.

Section 3006(f) of the Affordable Care Act, as added by section 10301(a) of the Affordable Care Act, requires CMS to develop a plan on implementing a value-based purchasing program for ASCs that will consider measures of quality and efficiency in ASCs, among other requirements. The Secretary must submit a report to Congress containing this plan not later than January 1, 2011.

H. Calculation of the ASC Conversion Factor and 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. 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, 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 amount. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative rate setting 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 under §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 the Office of Management and Budget in June 2003. The reclassification provision provided at section 1886(d)(10) of the Act is specific to hospitals. We believe the use of the most recent 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. For CY 2011, we have 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, for this type of unique situation, we are proposing to set the ASC wage index by calculating the average of all wage indices for urban areas in the state. In other situations, where there are no IPPS hospitals located in a relevant labor market area, we would 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 2011 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 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 2011 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2008 for CY 2011, we are proposing to compare the total payment weight using the CY 2010 ASC relative payment weights under the 75/25 blend (of the CY 2007 payment rate calculated under the ASC standard ratesetting methodology and the ASC payment rate calculated under the ASC standard methodology) with the total payment weight using the CY 2011 ASC relative payment weights (calculated under the ASC standard rate setting methodology) to take into account the changes in the OPPS relative payment weights between CY 2010 and CY 2011. We would use the ratio of CY 2010 to CY 2011 total payment weight (the weight scaler) to scale the ASC relative payment weights for CY 2011. The proposed CY 2011 ASC scaler is 0.9090 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 if a payment limitation did not apply) 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 2009 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 2009 ASC claims by provider and by HCPCS code. We created a unique supplier identifier solely for the purpose of identifying unique ASCs within the CY 2009 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 this 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 2011 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 (73 FR 41539). For CY 2011, we calculated this proposed adjustment for the ASC payment system by using the most recent CY 2009 claims data available and estimating the difference in total payment that would be created by introducing the CY 2011 pre-floor and pre-reclassified hospital wage indices. Specifically, holding CY 2009 ASC utilization and service-mix and CY 2010 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2010 pre-floor and pre-reclassified hospital wage indices and the total adjusted payment using the proposed CY 2011 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 2010 pre-floor and pre-reclassified hospital wage indices to the total adjusted payment calculated with the proposed CY 2011 pre-floor and pre-reclassified hospital wage indices and applied the resulting ratio of 1.0006 (the proposed CY 2011 ASC wage index budget neutrality adjustment) to the CY 2010 ASC conversion factor to calculate the proposed CY 2011 ASC conversion factor.

Section 1833(i)(2)(C) 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 CPI-U 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 amends 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 . . . 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. Section 3401(k) of the Affordable Care Act states that application of the MFP adjustment to the ASC payment system may result in the update to the ASC payment system being less than zero for a year and may result in payment rates under the ASC payment system for a year being less than such payment rates for the preceding year. We are proposing to revise §416.160 and §416.171 to reflect this provision of the Affordable Care Act.

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.

Table 54 provides illustrative examples of how the MFP would be applied to the ASC payment system. These examples show the implication of a positive CPI-U update factor with a small MFP, a positive CPI-U update factor with a large MFP adjustment, and a CPI-U update factor of 0. We discuss in greater detail the methodology for calculating the MFP for the ASC payment system and the other payment systems affected by the MFP adjustment (found in section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act) in the CY 2011 MPFS proposed rule. Comments on the specific mathematical calculation of the MFP should be made to that proposed rule. Comments on the application of the MFP to the CPI-U update factor under the ASC payment system should be made to this proposed rule.

TABLE 54: MULTIFACTOR PRODUCTIVITY ADJUSTED PAYMENT UPDATE: ILLUSTRATIVE EXAMPLES

CPI-U (Percent)	MFP (Percent)	MFP- Adjusted CPI-U Update Factor (Percent)
4.0	1.3	2.7
4.0	4.7	-0.7
0.0	0.2	-0.2

NOTE*:* Numbers may not sum due to rounding.

For this proposed rule, for the 12-month period ending with the midpoint of CY 2011, the Secretary estimates that the CPI-U is 1.6 percent. The Secretary estimates that the MFP adjustment is 1.6. As discussed in the CY 2011 MPFS proposed rule, we are proposing to reduce the CPI-U of 1.6 percent by the MFP adjustment specific to this

CPI-U, resulting in an MFP-adjusted CPI-U updated factor of 0 percent. Therefore, we are proposing to apply to the ASC conversion factor a 0 percent MFP-adjusted update.

For CY 2011, we also are proposing to adjust the CY 2010 ASC conversion factor ($41.873) by the wage adjustment for budget neutrality of 1.0006 in addition to the MFP-adjusted update factor of 0 discussed above, which results in a proposed CY 2011 ASC conversion factor of $41.898.

3. Display of Proposed ASC Payment Rates

Addenda AA and BB to this proposed rule display the proposed updated ASC payment rates for CY 2011 for covered surgical procedures and covered ancillary services, respectively. These addenda contain several types of information related to the proposed CY 2011 payment rates. Specifically, in Addendum AA, a "Y" in the column titled "Subject to Multiple Procedure Discounting" indicates that the surgical procedure would 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 proposed 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 2011.

The values displayed in the column titled “CY 2011 Payment Weight” are the proposed relative payment weights for each of the listed services for CY 2011. 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 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 2011 payment rate displayed in the “CY 2011 Payment” column, each ASC payment weight in the “CY 2011 Payment Weight” column is multiplied by the proposed CY 2011 conversion factor of $41.898. 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 2011 Payment Weight” column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The “CY 2011 Payment” column displays the proposed CY 2011 national unadjusted ASC payment rates for all items and services. The proposed CY 2011 ASC payment rates listed in the Addendum AA for separately payable drugs and biologicals are based on ASP data used for payment in physicians’ offices in April 2010.

XVI. Reporting Quality Data for Annual Payment Rate Updates

A. Background

1. Overview

CMS has implemented quality measure reporting programs for multiple settings of care. These programs promote higher quality, more efficient health care for Medicare beneficiaries. The quality data reporting program for hospital outpatient care, known as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP), has been generally modeled after the program for hospital inpatient services, 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 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 quality reporting program that is based on conditions for coverage.

2. Hospital Outpatient Quality Data Reporting under Section 109(a) of MIEA-TRHCA

Section 109(a) of the MIEA-TRHCA (Pub. L. 109-432) amended section 1833(t) of the Act by adding a new paragraph (17) which affects the annual payment update factor applicable to OPPS payments for services furnished by hospitals in outpatient settings on or after January 1, 2009. Section 1833(t)(17)(A) of the Act states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that fail to report data required for the quality measures selected by the Secretary in the form and

manner required by the Secretary under section 1833(t)(17)(B) of the Act will incur a 2.0 percentage point reduction to their annual payment update factor. 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)(A)(ii) of the Act specifies that any reduction would apply only to the payment year involved and would not be taken into account in computing the applicable annual payment update factor for a subsequent payment year.

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. The National Quality Forum (NQF) is a voluntary consensus standard setting organization that is composed of a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. NQF was established to standardize health care quality measurement and reporting through its consensus development process. We generally prefer to adopt NQF-endorsed measures for CMS quality reporting programs. However, we believe that consensus among affected parties also can be reflected by other means, including: consensus achieved during the measure development process; consensus shown through broad acceptance and use of measures; and consensus through public comment. We also note that section 1833(t)(17) of the Act

does not require that each measure we adopt for the HOP QDRP be endorsed by a national consensus building entity, or by the NQF specifically.

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 section 1886(b)(3)(B)(viii)" of the Act (the RHQDAPU program). As we stated in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68758 through 68759), we do not believe that we should, without further analysis, adopt the RHQDAPU program measures as the measures for the HOP QDRP. We continue to believe that it is most appropriate and desirable to adopt measures that specifically apply to the hospital outpatient setting for the HOP QDRP.

Section 1833(t)(17)(D) of the Act gives the Secretary the authority to replace measures or indicators as appropriate, such as when all hospitals are effectively in compliance or when 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 HOP QDRP available to the public. Such procedures include providing hospitals with the opportunity to review their data before these data are released to the public.

3. ASC Quality Data Reporting under Section 109(b) of MIEA-TRHCA

Section 109(b) of the MIEA-TRHCA amended section 1833(i) of the Act by redesignating 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 "so as to

provide for a reduction in any annual update for failure to report on quality measures" beginning with payment for ASC services furnished on or after January 1, 2009.

Section 1833(i)(7)(A) of the Act states that the Secretary may provide that any ASC that fails to report data required for the quality measures selected by the Secretary in the form and manner required by the Secretary under section 1833(i)(7) of the Act will incur a reduction in any annual payment update of 2.0 percentage points. Section 1833(i)(7)(A) of the Act also specifies that a reduction for one year cannot be taken into account in computing the annual ASC payment update 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, summarized above, shall apply to ASCs in a similar manner to the manner in which they apply under these paragraphs to hospitals under the HOP QDRP. We did not implement an ASC quality reporting program for CY 2008 (72 FR 66875) or for CY 2009 (73 FR 68780), or for CY 2010 (74 FR 60656).

We refer readers to section XVI.F. of this proposed rule for further discussion of ASC quality data reporting.

4. HOP QDRP Quality Measures for the CY 2009 Payment Determination

For the CY 2009 annual payment update, we required HOP QDRP reporting using seven quality measures--five Emergency Department (ED) Acute Myocardial Infarction (AMI) Cardiac Care measures and two Surgical Care measures. These measures address care provided to a large number of adult patients in hospital outpatient

settings across a diverse set of conditions, and were selected for the initial set of HOP QDRP measures based on their relevance as a set to all HOPDs.

Specifically, in order for hospitals to receive the full OPPS payment update for services furnished in CY 2009, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66865 and 66871), we required that subsection (d) hospitals paid under the OPPS submit data on the following seven measures for hospital outpatient services furnished on or after April 1, 2008: (1) ED-AMI-1: Aspirin at Arrival; (2) ED-AMI-2: Median Time to Fibrinolysis; (3) ED-AMI-3: Fibrinolytic Therapy Received within 30 Minutes of Arrival; (4) ED-AMI-4: Median Time to Electrocardiogram (ECG); (5) ED-AMI-5: Median Time to Transfer for Primary PCI; (6) PQRI #20: Surgical Care-Timing of Antibiotic Prophylaxis; and (7) PQRI #21: Surgical Care-Selection of Antibiotic.

5. HOP QDRP Quality Measures for the CY 2010 Payment Determination

For the CY 2010 payment update, we required continued submission of data on the existing seven measures discussed above (73 FR 68761), and adopted four new imaging measures (73 FR 68766). For CY 2010, we also changed the measure designations for the existing seven measures to an "OP-#" format. For example, the designations of ED-AMI-2 and ED-AMI-3 were changed to OP-1 and OP-2 so that the eleven measures for the CY 2010 payment update were designated as OP-1 through OP-11. This change allowed us to maintain a consistent sequential designation system that we could expand as we add additional measures.

The four imaging measures that we adopted beginning with the CY 2010 payment determination (OP-8: MRI Lumbar Spine for Low Back Pain, OP-9: Mammography Follow-up Rates, OP-10: Abdomen CT – Use of Contrast Material, and OP-11: Thorax CT - Use of Contrast Material) are claims-based measures that CMS will calculate using Medicare Part B claims data without imposing upon hospitals the burden of additional chart abstraction. For purposes of the CY 2010 payment determination, we will calculate these measures using CY 2008 Medicare administrative claims data.

In the CY 2009 OPPS/ASC proposed rule, OP-10 had two submeasures listed: OP-10a: CT Abdomen – Use of contrast material excluding calculi of the kidneys, ureter, and/or urinary tract, and OP-10b: CT Abdomen – Use of contrast material for diagnosis of calculi in the kidneys, ureter, and or urinary tract. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68766), we finalized OP-10 (previously known as OP-10a): Abdomen CT – Use of Contrast Material. To clarify, we are calculating OP-10 excluding patients with impaired renal functions because they are not candidates for an abdominal CT with contrast. This exclusion is described in greater detail in the Specifications Manual for Hospital Outpatient Department Quality Measures *(HOPD Specifications Manual)* located at the QualityNet Web site (http://www.QualityNet.org).

The complete set of 11 measures to be used for the CY 2010 payment determination is listed at 73 FR 68766.

6. HOP QDRP Quality Measures, Technical Specification Updates, and Data Publication for the CY 2011 Payment Determination

a. Quality Measures

For the CY 2011 payment determination, we required hospitals to continue to submit data on the existing 11 HOP QDRP measures. These measures continue to address areas of topical importance regarding the quality of care provided in HOPDs, and reflect consensus among affected parties. Seven of these 11 measures are chart-abstracted measures in two areas of importance that are also measured for the inpatient setting: AMI cardiac care and surgical care. The remaining four measures address imaging efficiency in HOPDs.

For the CY 2011 payment determination, we did not add any new HOP QDRP measures. We indicated our sensitivity to the burden upon HOPDs associated with chart abstraction and stated that we seek to minimize the collection burden associated with quality measurement. We also stated that we will continue to assess whether we can collect data on additional quality measures through mechanisms other than chart abstraction, such as from Medicare administrative claims data and EHRs.

The complete set of 11 measures that will be used for the CY 2011 payment determination is listed at 74 FR 60637.

b. Maintenance of Technical Specifications for Quality Measures

Technical specifications for each HOP QDRP measure are listed in the *HOPD 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 HOPD 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 updates to the technical specifications that we use to calculate HOP QDRP measures. This process is used when changes to the measure specifications are necessary due to changes in scientific evidence or in the measure as endorsed by the consensus entity. Changes of this nature may not coincide with the timing of our regulatory actions, but nevertheless require inclusion in the measure specifications so that the HOP QDRP measures are calculated based on the most up-to-date scientific and consensus standards. We indicated that notification of changes to the measure specifications on the QualityNet Web site, http://www.QualityNet.org, and in the HOPD Specifications Manual that occurred as a result of changes in scientific evidence or national consensus would occur no less than 3 months before any changes become effective for purposes of reporting under the HOP QDRP.

The HOPD Specifications Manual is released every 6 months and addenda are released as necessary providing at least 3 months of advance notice for insubstantial 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.

c. Publication of HOP QDRP Data

Section 1833(t)(17)(E) of the Act requires that the Secretary establish procedures to make data collected under the HOP QDRP program available to the public. It also states that such procedures must ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. To meet these requirements, data that a hospital has submitted for the HOP QDRP 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 encourages beneficiaries to work with their doctors and hospitals to discuss the quality of care hospitals provide to patients, thereby providing an additional incentive to hospitals to improve the quality of care that they furnish.

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 are available to CMS for reporting. However, information that may not be easily understood by the public and information with unresolved display issues or pending design considerations may be made 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 Hospital Compare Web site, allows CMS 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. We are

proposing that, under circumstances when we have to display hospital quality information on non-interactive CMS Web sites for reasons discussed earlier, affected parties would be notified via CMS listserves, 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. The release of preview reports allows CMS 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.

CMS also requires hospitals to complete and submit a registration form ("participation form") in order to participate in the HOP QDRP. With submission of this form, participating hospitals agree that they will allow CMS to publicly report the quality measures, including those that CMS calculates using Medicare claims, as required by the Act and the HOP QDRP.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68778), we established that, for CY 2010, hospitals sharing the same CMS Certification Number (CCN, previously known as the Medicare Provider Number (MPN)) must combine data collection and submission across their multiple campuses for the clinical measures for public reporting purposes. We finalized the policy that, under the HOP QDRP, we will publish quality data by the corresponding CCN. This approach is consistent with the approach taken under the RHQDAPU program. In the CY 2009 OPPS/ASC final rule with comment period, we also stated that we intend to indicate instances where data from

two or more hospitals are combined to form the publicly reported measures on the Web site.

In the CY 2010 OPPS/ASC final rule with comment period, we finalized our CY 2010 policy regarding publication of HOP QDRP data (74 FR 60652 through 60654). Section 1833(t)(17)(E) of the Act requires that the Secretary establish procedures to make data collected under the HOP QDRP available to the public; however, this section does not require that such data be validated before it is made public. We explained that, initially, we decided not to post "[i]nformation from non-validated data, including the initial reporting period (April – June 2008)" as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66874). We noted, however, that data submitted by hospitals are publicly reported regardless of whether those data are successfully validated for payment determination purposes under existing procedures for the RHQDAPU program. We also noted that, in the CY 2009 OPPS/ASC final rule with comment period, we stated that we intended to make the information collected under the HOP QDRP available to the public in 2010 (73 FR 68778).

In the CY 2010 OPPS/ASC proposed rule (74 FR 35404), we proposed to make data collected for quarters beginning with the third quarter of CY 2008 (July - September 2008) under the HOP QDRP publicly available, regardless of whether those data have been validated for payment determination purposes. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60654), we finalized our proposal to publicly report HOP QDRP data on Hospital Compare in 2010 with some modifications in the periods of time to be reported. For measures OP-1 through OP-5, we will publicly

report data periods beginning with the 3rd quarter of 2008. For measures OP-6 and OP-7, we will publicly report data periods beginning with the 3rd quarter of 2009. For measures OP-8 through OP-11, we will report CY 2010 payment determination calculations using CY 2008 claims.

B. Proposed Expansion of HOP QDRP Quality Measures for the CY 2012, CY 2013, and CY 2014 Payment Determinations

1. Considerations in Expanding and Updating Quality Measures under the HOP QDRP

In general, when selecting measures for the HOP QDRP 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 HOP QDRP 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 HOP QDRP program.

Specifically, we give 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 have used and continue to use these criteria to guide our decisions regarding what measures to add to the HOP QDRP 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 HOP QDRP 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[1] and EHRs as alternative ways to collect data from hospitals. 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 HOP QDRP 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 HOP QDRP, and would be publicly reported like other HOP QDRP 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.

[1] A registry is a collection of clinical data for purposes of assessing clinical performance, quality of care, and opportunities for quality improvement.

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). CMS has adopted the definition of Qualified EHR set forth by the Office of the National Coordinator for Health Information Technology (ONC) which has adopted the statutory definition of Qualified EHR as follows: Section 3000(13) of the PHSA defines 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". CMS has also adopted the definition of Certified EHR by ONC as follows: Certified EHR technology means a complete EHR or a combination of EHR Modules, each of which: (1) Meets the requirements included in the definition of a Qualified EHR; and (2) has been tested and certified in accordance with the certification program established by the ONC as having met all applicable certification criteria adopted by the Secretary. Establishing a data submission mechanism using EHRs system will require interoperability between EHRs and CMS 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 HOP QDRP 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.

In prior years, we have proposed measures for one payment determination in a given rulemaking cycle. In prior rules, we have identified measures for future consideration, but have not proposed or finalized measures beyond those to be collected and used for the next sequential payment determination. In this CY 2011 rulemaking cycle, we are proposing the addition of new measures over a three year period of time for CY 2012, CY 2013, and CY 2014 payment determinations. We believe this proposed process would assist hospitals 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. To the extent that we choose to finalize some or all of these measures for the CY 2012, CY 2013 and CY 2014 payment determinations, this would not preclude us from proposing additional measures or changing the list of measures for future payment determinations through subsequent rulemaking cycles that affect these future payment determinations. We invite comments on our intention to propose measures for more than one payment determination in a single rulemaking cycle.

2. Retirement of HOP QDRP Quality Measures

In the FY 2010 IPPS/RY 2010 LTCH PPS proposed rule, we finalized a process for immediate retirement of RHQDAPU program measures based on evidence that the continued use of the measure as specified raises patient safety concerns (74 FR 43864 through 43865). In circumstances such as those prompting immediate retirement of the

AMI-6 measure from the RHQDAPU program in December 2008 as discussed in the FY 2010 IPPS/LTCH final rule (74 FR 43864 through 43865) we do not believe that it would be appropriate to wait for the annual rulemaking cycle to retire a measure. We adopted this same immediate retirement policy for the HOP QDRP in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60635).

Specifically, we stated that if we receive evidence that continued collection of a measure that has been adopted for the HOP QDRP raises patient safety concerns, we would promptly retire the measure and notify hospitals and the public of the retirement of the measure and the reasons for its retirement through the usual means by which we communicate with hospitals, including but not limited to hospital e-mail blasts and the QualityNet Web site. We also stated that we would confirm the retirement of a measure retired in this manner in the next OPPS rulemaking cycle. However, for other circumstances in which we do not believe that continued use of a measure raises specific patient safety concerns, we stated that we intend to use the regular rulemaking process to retire a measure.

3. Proposed HOP QDRP Quality Measures for the CY 2012 Payment Determination

a. Proposed Retention of Existing HOP QDRP Measures for the CY 2012 Payment Determination

For the CY 2012 payment determination, we are proposing to retain the existing 11 HOP QDRP measures. These measures continue to address areas of topical importance regarding the quality of care provided in HOPDs, and reflect consensus among affected parties. Seven of these 11 measures are chart-abstracted measures in two

areas of importance that are also measured for the inpatient setting: AMI cardiac care and surgical care. The remaining four measures are claims-based measures that address imaging efficiency in HOPDs.

We invite public comment on our proposal to retain the existing 11 HOP QDRP measures for the CY 2012 payment determination.

b. Proposed New Structural Measure for CY 2012 Payment Determination

For the CY 2012 payment determination, we are proposing to add one structural measure: "Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data" (NQF # 0489). Structural measures allow the assessment of the conduciveness of the provider environment to processes and technologies that enable delivery of high quality care. This particular structural measure assesses the extent to which a provider uses a certified/qualified EHR system that incorporates an electronic data interchange with one or more laboratories allowing for direct electronic transmission of laboratory data into the EHR as discrete searchable data elements. We believe that electronic transmission of laboratory data into EHRs would enable greater timeliness of results reporting, because the results of the reports would be transmitted to the HOPD as soon as the laboratory data are available and be merged with clinical information for more timely clinical assessments, and laboratory value alerts. Electronic transmission of laboratory data would also lead to cost efficiency, expedite the clinical decision process, and reduce redundancy of laboratory orders, and reduce human errors. 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. As discussed above, this structural measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because it was endorsed in 2008 as part of an NQF project entitled "National Voluntary Consensus Standards for Health Information Technology: Structural Measures." Additionally, this measure was conditionally adopted by the Hospital Quality Alliance (HQA) in 2010. (The HQA is a public-private collaboration to improve the quality of care provided by the nation's hospitals by measuring and publicly reporting on that care.)

We are proposing that this structural measure would be submitted by HOPDs beginning with January 1, 2011 discharges via a Web-based tool available on the QualityNet Web site that is currently employed for the collection of structural measures for the RHQDAPU program. For this structural measure, HOPDs would submit the number of encounters out of all encounters for which laboratory results were documented in the EHR. We invite comments on our proposal to add this new structural measure to the HOP QDRP measurement set and the submission process for the CY 2012 payment determination.

c. Proposed New Claim-Based Measures for CY 2012 Payment Determination

For the CY 2012 payment determination, we are proposing to add four new claims based imaging efficiency measures to the HOP QDRP measurement set, all of which

were listed as under consideration for CY 2012 and subsequent years in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60637 through 60641). Imaging efficiency is a new area of measurement that we first implemented in the HOP QDRP for the CY 2010 payment determination and subsequently retained for the CY 2011 payment determination. There are currently four existing claims based imaging efficiency measures in the HOP QDRP measurement set (OP-8 through OP-11). The four new proposed imaging efficiency measures for the CY 2012 payment determination are: 1) Pre-operative Evaluation for Low-Risk Non-Cardiac Surgery Risk Assessment, 2) Use of Stress Echocardiography, SPECT MPI, and Cardiac Stress MRI post CABG, 3) Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT), and 4) Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache.

Like the current imaging efficiency measures in the HOP QDRP measurement set, these four measures are based on Medicare claims and will not require additional data submission on the part of hospitals. All four of these proposed measures are currently undergoing NQF review, and specifications for these measures are available at www.imagingmeasures.com.

The first new proposed imaging efficiency measure for the CY 2012 payment determination seeks to calculate relative use of stress echocardiography, stress MRI, and SPECT MPI prior to low-risk non-cardiac surgical procedures in the 30 days preceding the surgery. The second new proposed claim-based imaging efficiency measure for the CY 2012 payment determination seeks to estimate relative use of stress echocardiography

and SPECT MPI in asymptomatic patients less than five years after a coronary artery bypass graft (CABG) procedure.

Cardiac imaging is a gap area that was not addressed in CMS' first set of Outpatient Imaging Efficiency measures. It is among the most common imaging services in the Medicare population. In the hospital outpatient setting, 762,419 SPECT MPI, Stress MRI and Stress Echocardiography procedures were performed in 2008 alone.[2] Further, between 1998 and 2006, the rate of myocardial perfusion imaging (MPI) use in Medicare beneficiaries increased 51 percent among cardiologists in the hospital setting, and by 215 percent in private offices. During the same time period, total Medicare Part B payments for MPI across all settings of care increased by 227 percent.[3]

SPECT MPI, Stress MRI, and Stress Echocardiography are specific procedures that must be ordered by a physician to be performed. Therefore, there is a distinct opportunity for the physician to order this procedure prudently based on best practices. While SPECT MPI, Stress MRI, and Stress Echocardiography enhance the quality of care when used appropriately, inappropriate usage of imaging would cause unnecessary waste of services, contribute no benefit to the quality of care, and could increase the patient's risk of cancer. An analysis by Gibbons et al.[4] found that, of all SPECT MPI procedures performed at the Mayo Clinic Rochester in May 2005, 14 percent were considered inappropriate using criteria published by the American College of Cardiology Foundation and the American Society of Nuclear Cardiology, and an additional 11 percent were of

[2] The Lewin Group analysis of Medicare Calendar Year 2007 claims data prepared for the Centers for Medicare & Medicaid Services, HHS Contract No: HHSM-500-2005-0024I, Order No. 0002.
[3] Levin DC, Rao VM, Parker L, et al. Recent payment and utilization trends in radionuclide myocardial perfusion imaging: Comparison between self-referral and referral to radiologists. J Am Coll Radiol 2009;6:437-441.

indeterminate appropriateness.[4] This study also found that during the same time period, 18 percent of all stress echocardiograms performed were inappropriate, and an additional 9 percent were indeterminate.

The third and fourth new proposed imaging efficiency measures for the CY 2012 payment determination pertain to appropriate use of Brain CT imaging in HOPDs. These are "Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)," and "Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache."

A recent report in the New England Journal of Medicine[5] raised serious concerns about the use and overuse of CT scanning, stating that for an estimated 62 million CT scans being performed per year, a third are unnecessary, resulting in patient safety issues including unnecessary radiation and contrast material exposure, and the danger associated with "false positive" findings. A CT scan exposes the patient to higher doses of radiation than a conventional x-ray and increases the patient's risk of cancer.

Brain CTs are often ordered in addition to a sinus CT for patients with sinusitis because headache is a common symptom related to sinusitis. However, simultaneous CT sinus and brain imaging for headache without suspected complications is generally considered inappropriate, as the standard anatomic coverage of a CT of the head includes large portions of the paranasal sinuses; thus, ordering both procedures is duplicative and

[4] Gibbons RJ, Miller TD, Hodge D, et al. Application of appropriateness criteria to stress single-photon emission computed tomography sestamibi studies and stress echocardiograms in an academic medical center. J Am Coll Cardiology 2008;51:1283-9.
[5] Brenner DJ, Hall EJ. November 29, 2007. Computer Tomography – An Increasing Source of Radiation Exposure. New England J of Medicine 2007:357(22): 2277-84.

inefficient.[5,6] The third new proposed imaging efficiency measure for the CY 2012 payment determination "Simultaneous Use of Brain CT and Sinus CT" assesses the extent to which patients with a headache who have a brain CT also have a sinus CT performed on the same date at the same facility. The measure excludes patients with trauma diagnoses, tumors or orbital cellulitis.

The fourth new proposed imaging efficiency measure for the CY 2012 payment determination, "Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache," assesses the extent to which patients presenting with a headache receive brain CT studies. The measure excludes patients admitted or transferred to an acute care hospital, patients with lumbar punctures, dizziness, paresthesia, lack of coordination, subarachnoid hemorrhage or thunderclap headaches. The lifetime prevalence of headache is over 90 percent for men and women and according to some studies, headache accounts for 16 million physician visits in the U.S. annually.[7] According to a study conducted by Goldstein et al. (2006) on U.S. emergency departments (EDs) from 1992 to 2001, headaches represent approximately 2 percent of U.S. ED visits.[8] An analysis of 2007 Medicare claims data found that approximately 200,000 Medicare beneficiaries had a visit to an ED with a primary diagnosis of headache with about half of these patients (not taking into account the previously mentioned exclusion of lumbar punctures, dizziness, paresthesia, lack of coordination,

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[5] Brenner DJ, Hall EJ. November 29, 2007. Computer Tomography – An Increasing Source of Radiation Exposure. New England J of Medicine: 357(22): 2277-84.

[6] Appropriateness Criteria – Headache. Reston, VA: American College of Radiology, 2009. Accessed November 25, 2009 at http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria.aspx

[7] Mellion ML, Jayaraman MV. August 2007. Use of neuroimaging in the workup of headache. Med Health R I.; 90(8):249-50.

[8] Goldstein JN, CA Camargo, AJ Pelletier, JA Edlow. 2006. Headache in the United States Emergency Departments: demographics, work-up and frequency of pathological diagnoses. Cephalalgia; 26(6) 684.

subarachnoid hemorrhage or thunderclap headaches) receiving a Brain CT coincident with the ED visit.[9] Unnecessary or duplicative studies are inefficient and detrimental to the patient because CT exposes the patient to higher doses of radiation than conventional x-ray and increases the patient's risk for cancer.[10]

Concern over the inappropriate use of CT Imaging in the ED setting has been driven by three primary factors: false positive interpretations, radiation exposure, and cost. There is generally a lower threshold for ordering neuro-imaging for headache in the ED because of physician time constraints and lack of ED physician familiarity with headache presentation.[11] Because of this lower threshold, the measurement of the use of CT Brain in the ED for patients with a diagnosis of atraumatic headache can help to raise the awareness of the need for quality improvement on the appropriate use of CT brain imaging in the ED and, as a result improve patient safety through reduction in unnecessary radiation exposure.

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. As discussed above, these measures are appropriate for measuring quality of care in the hospital outpatient department setting. These measures also meet the consensus requirement because these measures underwent

[9] The Lewin Group analysis of Medicare Calendar Year 2007 claims data prepared for the Centers for Medicare & Medicaid Services, HHS Contract No: HHSM-500-2005-0024I, Order No. 0002.
[10] Brenner DJ and Hall EJ. November 29, 2007. Computed Tomography — An Increasing Source of Radiation Exposure. N Engl J Med;357(22):2277-84..
[11] Ward TN, Leven M, Phillips JM. Evaluation and management of headache in the emergency department. Med Clin N Am 2001; 85(4) 971-85.

development through a consensus-based measure development process involving stakeholder input. We anticipate that they will be endorsed by the NQF.

For the CY 2012 payment determination, we are proposing to calculate these four measures using Medicare claims from CY 2010. We invite comments on our proposal to add these four new imaging efficiency measures to the HOP QDRP measurement set based on Medicare claims from CY 2010 for the CY 2012 payment determination.

d. Proposed New Chart-Abstracted Measures for CY 2012 Payment Determination

We are proposing to add one new chart-abstracted measure to the HOP QDRP measurement set for the CY 2012 payment determination: "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." Troponin is used to help diagnose a heart attack, to detect and evaluate mild to severe heart injury, and to distinguish chest pain that may be due to other causes.

This measure is based upon the existing ED-AMI/Chest Pain populations for which we have adopted five measures in the current HOP QDRP measurement set. This measure is currently undergoing NQF review.

Both patients and clinicians are impacted by the timeliness of laboratory reporting.[12] Decreasing laboratory turnaround times increases ED efficiency, specifically by decreasing diversion time from treatment of patients and decreasing length of stay.[13] Decreasing the numbers of hours a day on diversion as well as decreasing patients'

[12] Howanitz JH, and Howanitz PJ. Laboratory results: Timeliness as a quality attribute and strategy. Am J Clin Pathol. 2002 Sep;116(3):311-5.

[13] Storrow AB, Zhou C, Gaddis G, Han JH, Miller K, Klubert D, Laidig A, and Aronsky D. Decreasing lab turnaround time improves emergency department throughput and decreases emergency medical services diversion: A simulation model. Acad Emerg Med. 2008 Nov;15(11):1130-5.

lengths of stay in EDs allows for the treatment of a greater number of patients. Studies have found correlations between the length of stay and mean turnaround times.[14] Efficiencies in throughput with tasks can lead to less diversion, less overcrowding, less elopements and less financial loss.[15] 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. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because this measure underwent development through a consensus-based measure development process involving stakeholder input. We anticipate that this measure will be endorsed by the NQF.

If adopted, data collection for this measure would begin with January 1, 2011 discharges, and data would be submitted quarterly beginning with the first quarter of 2011, as with all other chart-abstracted measures.

We invite public comment on our proposal to add this new chart-abstracted measure to the HOP QDRP measurement set and the submission process for the CY 2012 payment determination.

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[14] Holland LL, Smith LL, and Blick KE. Reducing laboratory turnaround time outliers can reduce emergency department length of stay: An 11-hospital study. Am J Clin Pathol. 2005 Nov;124(5):672-4.
[15] Falvo T, Grove L, Stachura R, and Zirkin W. The financial impact of ambulance diversions and patient elopements. Acad Emerg Med. 2007 Jan;14(1):58-62.

In summary, for the CY 2012 payment determination, we are proposing to retain the 11 existing HOP QDRP measures for the CY 2011 payment determination, to add one new structural measure, four new claims-based imaging efficiency measures, and one new chart-abstracted measure for the ED AMI population. Submission of data regarding the new structural measure would begin with January 1, 2011 discharges using a Web-based collection tool available on the QualityNet Web site. We are proposing to calculate the four imaging measures using Medicare claims from calendar year 2010. Data collection for the chart-abstracted measure would begin with January 1, 2011 discharges, and data would be submitted quaterly beginning with the first quarter of 2011, as with all other chart-abstracted measures. We invite public comment on this proposal for the CY 2012 payment determination.

The complete list of 17 proposed measures for the CY 2012 payment determination is shown below.

Proposed HOP QDRP Measurement Set to be Used for the CY 2012 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

Proposed HOP QDRP Measurement Set to be Used for the CY 2012 Payment Determination
The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data*
Preoperative Evaluation for Low Risk Non Cardiac Surgery Risk Assessment*
Use of Stress Echocardiography, SPECT MPI, and Cardiac Stress MRI post CABG*
Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)*
Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache*
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.*

* Proposed new measure for CY 2012 payment determination

4. Proposed HOP QDRP Quality Measures for the CY 2013 Payment Determination

a. Proposed Retention of CY 2012 HOP QDRP Measures for the CY 2013 Payment Determination

In general, unless otherwise specified in the retirement section of a rule, we retain measures from one payment determination to another. For the CY 2013 payment determination, we are proposing to retain all of the measures adopted for the CY 2012 payment determination. We invite public comment on this proposal for the CY 2013 payment determination.

b. Proposed New Structural Measure for the CY 2013 Payment Determination

We are proposing to add one structural measure to the HOP QDRP measurement set for the CY 2013 payment determination: Tracking Clinical Results between Visits. EHRs enable providers to issue reminders when clinical results are not received within a predefined timeframe. This measure assesses the extent to which a provider uses a certified/qualified EHR system to track pending laboratory tests, diagnostic studies (including common preventive screenings) or patient referrals. 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. As discussed above, this structural measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because it was endorsed as part of an NQF Project entitled "National Voluntary Consensus Standards for Health IT" (NQF # 0491). Additionally, this measure was conditionally approved by the HQA in March of 2010.

Submission of this measure would begin with first quarter CY 2012 discharges to be submitted via the Web-based tool used to collect other structural measures, such as the registry participation structural measures for the RHQDAPU program. We invite comments on this proposal to add this new structural measure to the HOP QDRP measurement set and the submission process for the CY 2013 payment determination.

c. Proposed New Chart-Abstracted Measures for the CY 2013 Payment Determination

We are proposing to add six new chart-abstracted measures to the HOP QDRP measurement set for the CY 2013 payment determination.

The six new chart-abstracted measures we are proposing for the CY 2013 payment determination are: 1) Median Time from ED Arrival to ED Departure for Discharged ED Patients, 2) Transition Record with Specified Elements Received by Discharged Patients, 3) Door to Diagnostic Evaluation by a Qualified Medical Professional, 4) ED- Median Time to Pain Management for Long Bone Fracture, 5)

ED-Patient Left Before Being Seen, and 6) ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Who Received Head CT Scan Interpretation Within 45 minutes of Arrival. The topics addressed by these measures include ED efficiency, Imaging Efficiency, and care coordination/transition for hospital outpatient departments. Many of these measures would expand the chart-abstraction population for the HOP QDRP measurement set beyond the current ED-AMI/Chest Pain, and Surgical Care patients for which we have currently adopted seven measures in the HOP QDRP measurement set. However, this population expansion would be occurring at a time when subsection (d) hospitals would begin collection of more global ED population measures for the RHQDAPU program. Thus, we have timed the expansion of the chart-abstracted measures for HOP QDRP to coincide with expansions that will be occurring for the RHQDAPU program in order to reduce the burden associated with expansion. We also anticipate that, in the future, these measures could be captured and submitted via EHRs, eliminating the chart abstraction burden associated with these measures. These measures are discussed below:

(1) Median Time from ED Arrival to ED Departure for Discharged ED Patients

This measure, which was listed as under consideration for CY 2012 and subsequent years in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60637 through 60641), addresses ED efficiency in the form of the median time from emergency department arrival to time of departure from the emergency room for patients discharged from the emergency department. Reducing the time patients spend in the ED can improve quality of care. Reducing this time potentially improves access for

more patients needing emergency care and increases hospitals' capability to provide additional treatment as necessary. Overcrowding and heavy emergency resource demand have led to a number of problems, including ambulance refusals, prolonged patient waiting times, increased suffering for those who wait, rushed and unpleasant treatment environments, and potentially poor patient outcomes. ED crowding may result in delays in the administration of medication such as antibiotics for pneumonia and has been associated with perceptions of delayed emergency care. When EDs are overwhelmed, their ability to respond to community emergencies and disasters may be compromised. 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. As discussed above, this chart-abstracted measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because it was endorsed in 2009 (NQF # 0496) as part of an NQF project entitled "National Voluntary Consensus Standards for Emergency Care." Additionally, this measure was conditionally approved by the HQA in March of 2010.

(2) Transition Record with Specified Elements Received by Discharged Patients

This chart-abstracted measure assesses the percentage of patients, regardless of age, discharged from an ED to ambulatory care or home healthcare, or their caregiver(s), who received a transition record at the time of ED discharge including at a minimum, the

following elements: major procedures and tests performed during the ED visit; principal diagnosis at discharge or chief complaint; patient instructions; plan for follow-up care (or statement that none is required) - including primary physician, other health care professional, or site designated for follow-up care; and list of new medications and changes to continued medications that patient should take after ED discharge, with the quantity prescribed and/or dispensed (or intended duration) and instructions for each. Transitions of care are a weakness in maintaining continuity of care and proper adherence/compliance with follow up instructions. Hand-offs between settings should be accompanied by clear instructions for medications and follow- up care. Information should be provided about the care delivered while in each setting, and for what reasons, not only for the benefit of the patient and their caregivers, but for practitioners that will be following up with the patient after they leave an acute care setting.

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. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because it was endorsed by the NQF as part of a Project entitled “Endorsing Preferred Practices and Performance Measures for Measuring and Reporting Care Coordination” (NQF # 0649). This measure was conditionally approved by the HQA in March of 2010.

(3) Door to Diagnostic Evaluation by a Qualified Medical Professional (Door to Provider)

This measure assesses mean time between patient presentation to the ED and the first moment the patient is seen by a person who can initiate a diagnostic evaluation or therapeutic plan (for example, medical student, resident, nurse practitioner; excludes triage personnel). Long wait times in the ED before diagnosis increases the likelihood that someone will leave the ED without treatment for a serious condition, and can worsen the severity of the condition with which they presented. 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. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because it gained NQF endorsement as part of the project entitled "National Voluntary Consensus Standards for Emergency Care" (NQF # 0498). This measure was conditionally approved by the HQA in March of 2010.

(4) ED- Median Time to Pain Management for Long Bone Fracture

This chart-abstracted measure addresses the topic of efficient pain management in the ED, and is currently being reviewed by NQF. Pain management in patients with long bone fractures is currently undertreated in emergency departments.[16] Patients with bone

[16] Ritsema, T.S., Kelen, G.D., Pronovost, R.J., and Pham, J.C.: The national trend in quality of emergency department pain management of long bone fractures. Acad Emerg Med. 2007 Feb 14; 14(2):163-9.

fractures continue to lack administration of pain medication as part of treatment regimens.[17] When standards are implemented for pain management of these patients, treatment for pain improve.[18] 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. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because it underwent development through a consensus-based measure development process involving stakeholder input. We anticipate that this measure will be endorsed by the NQF.

(5) ED- Patient Left Without Being Seen

This measure is the sum of all patients leaving an ED who were not seen by a provider (for example, medical student, resident, nurse practitioner). A patient leaving before being seen is an indicator of emergency department overcrowding.[19] Patients who leave before being seen may not receive appropriate medical care and this lack of care may result in adverse outcomes.[20] National estimates for patients who leave before being

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[17] Brown, J.C., Klein, E.J., Lewis, C.W., Johnston, B.D., and Cummings, P.: Emergency department analgesia for fracture pain. Ann Emerg Med. 2003 Aug;42(2):197-205.

[18] **Titler, M.G., Herr, K., Brooks, J.M., Xie, X.J., Ardery, G., Schilling, M.L., Marsh, J.L., Everett, L.Q., Clark, W.R: Translating research into practice intervention improves management of acute pain in older hip fracture patients.** *Health Serv Res. 2009***;44(1),264-87.**

[19] United States General Accounting Office. Hospital emergency departments: Crowded conditions vary among hospitals and communities. Publication GAO-03-460, 2003.

[20] Rowe, B.H., Channan, P., Bullard, M., Blitz, S., Saunders, L.D., Rosychuk, R.J., Lari, H., Craig, W.R., Holroyd, B.R.: Characteristics of patients who leave emergency departments without being seen. Acad Emerg Med. 2006 Aug;13(8):848-52.

seen by a provider average 1.9 percent.[21] 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. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because it was endorsed by the NQF (NQF # 0499) as part of the National Voluntary Consensus Standards for Emergency Care.

(6) ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Who Received Head CT Scan Interpretation within 45 minutes of Arrival

This measure assesses whether head CT scan results for acute ischemic stroke or hemorrhagic stroke patients who received head CT scans in the ED were interpreted within 45 minutes of arrival. This chart-abstracted measure is currently under NQF review. Improved access to diagnostics assists clinicians in decision making. Delayed diagnostic imaging and laboratory reports are expected to slow down clinical decision making process and subsequently increase length of stay in the ED. Similarly, decreasing radiology report turnaround times can have impacts across the facility and can assist in reducing the length of stay in the ED. It also can enhance decision making capabilities for patient treatment plans because timely diagnostic imaging is available.[22] The Food

[21] McCaig, L.F., Nawar, E.W.: National hospital ambulatory medical care survey: 2004 Emergency department summary. Adv Data. 2006 Jun 23;(372):1-29.

[22] Marquez L.O. Improving medical imaging report turnaround times. Radiol Mange. 2005 Jan-Feb;27(1):34-7.

and Drug Administration (FDA) approved the use of tissue plasminogen activator (t-PA) for treatment of acute ischemic stroke, which comprise 87 percent of stokes, when given within three hours of stroke symptom onset.[23,24] Because of the therapeutic time window for treatment possibilities, timely completion and results of the CT scan are imperative for timely clinical decision making and favorable outcomes. 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. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because this measure underwent development through a consensus-based measure development process involving stakeholder input. We anticipate that this measure will be endorsed by the NQF.

The submission of the new chart-abstracted measures for the CY 2013 payment determination will begin with first quarter 2012 discharges, and data would be submitted quarterly, as with all other chart-abstracted measures. We invite comments on this proposal to add these new measures to the HOP QDRP measurement set and on the submission process for the CY 2013 payment determination.

In summary, for the CY 2013 payment determination, we are proposing to retain all of the measures adopted for the CY 2012 payment determination, and to adopt one

[23] National Stroke Association. STROKE the First Hours Guidelines for Acute Treatment, 2000.
[24] The ATLANTIS, ECASS, and NINDS rt-PA Study Group Investigators. Association of Outcome with early stroke treatment: pooled analysis of ATLANTIS, ECASS, and NINDS rt-PA stroke Trials. Lancet 2004;363:768-774.

new structural measure, and six new chart-abstracted measures for the CY 2013 payment determination on the topics of HOPD care transitions and ED efficiency. Submission of the new structural measure would begin with first quarter CY 2012 discharges to be submitted via a Web-based tool on the QualityNet Web site in 2012. The submission of the new chart-abstracted measures for the CY 2013 payment determination would begin with first quarter CY 2012 discharges, to be submitted in 2012. We invite comments on this proposal for the CY 2013 payment determination.

The complete list of 24 proposed measures for the CY 2013 payment determination is shown below.

Proposed HOP QDRP Measurement Set to be Used for the CY 2013 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
The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data*
Preoperative Evaluation for Low Risk Non Cardiac Surgery Risk Assessment*
Use of Stress Echocardiography, SPECT MPI, and Cardiac Stress MRI post CABG*
Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)*
Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache*
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 *

Proposed HOP QDRP Measurement Set to be Used for the CY 2013 Payment Determination
Tracking Clinical Results between Visits**
Median Time from ED Arrival to ED Departure for Discharged ED Patients**
Transition Record with Specified Elements Received by Discharged Patients**
Door to Diagnostic Evaluation by a Qualified Medical Professional**
ED- Median Time to Pain Management for Long Bone Fracture **
ED- Patient Left Before Being Seen**
ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival **

* Proposed new measure for CY 2012 payment determination
** Proposed new measure for CY 2013 payment determination

5. Proposed HOP QDRP Quality Measures for the CY 2014 Payment Determination

a. Proposed Retention of CY 2013 HOP QDRP Measures for the CY 2014 Payment Determination

In general, unless otherwise specified in the retirement section of a rule, we retain measures from one payment determination to another. For the CY 2014 payment determination, we are proposing to retain all of the measures adopted for the CY 2013 payment determination. We invite comment on this proposal.

b. Proposed New Chart-Abstracted Measures for the CY 2014 Payment Determination

We are proposing to adopt six new chart-abstracted measures for the CY 2014 payment determination. Five of the six measures are Diabetes Care measures for HOPDs, and one measure is an additional imaging efficiency measure. The six measures we are proposing for the CY 2014 payment determination are: (1) Hemoglobin A1c Poor Control in Diabetic Patients; (2) Low Density Lipoprotein (LDL-C) Control in Diabetic Patients; (3) High Blood Pressure Control in Diabetic Patients; (4) Dilated Eye Exam in Diabetic Patients; (5) Urine Screening for Microalbumin or Medical Attention for

Nephropathy in Diabetic Patients; and (6) Exposure Time Reported for Procedures Using Fluoroscopy. We are proposing that submission of these measures for the CY 2014 payment determination begin with the first quarter CY 2013 discharges to be submitted in 2013. These measures are discussed below.

(1) Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetic Patients

This NQF-endorsed measure (NQF # 0059) measures the percentage of adult patients with diabetes aged 18-75 years with most recent HgA1c level greater than 9 percent (poor control). Glycosylated hemoglobin (HgA1c) assay measures average blood glucose over the preceding two to three months, rather than just one point in time. HgA1c values vary less 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. Lowered HgA1c levels are associated with reduced microvascular and neuropathic complications of diabetes.

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.[25] 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

[25] 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. HgA1c should be performed during an initial assessment and during follow-up assessments, which should occur at no longer than three-month intervals.[26] 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. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because, as noted above, it has been endorsed by the NQF.

(2) Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetic Patients

This NQF-endorsed measure (NQF # 0064) measures the percentage of adult patients with diabetes aged 18-75 years whose most recent LDL-C test result during the measurement year was < 100 mg/dl. LDL-C measures the development of atherosclerotic plague which increases cardiac events risks for diabetic patients whose heart disease death rates are about two to four times higher than non-diabetics.[27] Improved dyslipidemia management helps to mitigate the risk for cardiovascular disease.

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[26] The American Association of Clinical Endocrinologists Medical Guidelines for the Management of Diabetes Mellitus: The AACE System of Intensive Diabetes Self-Management -2002 Update.

[27] American Diabetes Association. Standards of medical care in diabetes. Diabetes Care. 2007 Jan;30 (Suppl 1):S8-15.

Lipid-lowering therapy for diabetics has been a consistent recommendation in several 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.[28] Early treatment may help 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. 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. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because, as noted above, it has been endorsed by the NQF. We also note that this measure was listed as under consideration for CY 2012 and subsequent years in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60637 through 60641).

(3) Diabetes Mellitus: High Blood Pressure Control in Diabetic Patients

This NQF-endorsed measure (NQF # 0061) measures the percentage of patients visits with blood pressure measurement recorded among all patients visits aged > 18 years with diagnosed hypertension. Blood pressure control reduces the risk of

[28] 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.

cardiovascular disease and microvascular complications in patients with diabetes. Most importantly, early treatment of high blood pressure may help slow or halt the progression of kidney involvement and damage.[29] Blood pressure is a factor that can be controlled 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. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because, as noted above, it has been endorsed by the NQF.

(4) Diabetes Mellitus: Dilated Eye Exam in Diabetic Patients

This NQF-endorsed measure (NQF # 0055) 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 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. A

[29] 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.

dilated eye exam helps to detect the risk for vision-threatening diabetic retinopathy which is prevalent among people with diabetes. Data from the 2007 National Diabetes Fact Sheet (using the most recent year of available data) shows that diabetic retinopathy causes up to 24,000 new cases of blindness each year.[30] However, dilated eye exams for diabetic patients can prevent retinopathy through early detection.[31]

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. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because, as noted above, this measure has been endorsed by the NQF. We note that this measure was listed as under consideration for CY 2012 and subsequent years in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60637 through 60641).

(5) Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients

This NQF-endorsed measure (NQF # 0062) measures the percentage of adult diabetic patients aged 18 – 75 years with at least one test for microalbumin during the measurement year or who had evidence of medical attention for existing nephropathy

[30] 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.

[31] American Diabetes Association. Standards of medical care in diabetes. Diabetes Care. 2007 Jan;30 (Suppl 1):S8-15.

(diagnosis of nephropathy or documentation of microalbuminuria or albuminuria). Urine screening for microalbumin detects 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. Early urine screenings for microalbumin may prevent kidney disease from worsening to end-stage renal disease (ESRD). 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.[32] In 2009, MedPAC reported costs for the 330,000 Medicare recipients receiving dialysis treatment for ESRD at over 8 billion dollars.[32] 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. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because, as noted above, it has been endorsed by the NQF. We also note that this measure was listed as under consideration for CY 2012 and subsequent years in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60637 through 60641).

[32] 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.

[32] MedPAC. Outpatient dialysis service: assessing payment adequacy and updating payments. Report to the Congress: Medicare payment policy. 2009 Mar;131-56.

(6) Exposure Time Reported for Procedures Using Fluoroscopy

This measure documents the percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time, an important measure for the HOPD setting. This measure is currently specified for physician level data collection through the PQRI program (74 FR 61825), and can be used for the hospital outpatient facility level. This measure evaluates the documentation of radiation exposure or radiation time during fluoroscopy. Data suggests that the lifetime risk for cancer can be increased, albeit by a small amount, with frequent or repeated exposure to ionizing radiation, including procedures using fluoroscopy.[33] To monitor these long term effects, the exposure time or radiation dose that a patient receives as a result of the procedure should be measured and recorded in the patient's record. The American College of Radiology (ACR) encourages practices to record actual fluoroscopy time for all fluoroscopic procedures. The fluoroscopy time for various procedures (for example, upper gastrointestinal, pediatric voiding cystourethrography) should then be compared with benchmark figures.[34,35] The National Cancer Institute also recommends measuring and recording patient radiation dose, fluoroscopy time and additional available measures: dose area product, cumulative dose, and skin dose.[37] Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures

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[33] National Cancer Institute (NCI), The Society for Pediatric Radiology (SPR). Brochure: Radiation & pediatric computed tomography. A guide for health care providers. 2002. Available at; http://www/cancer.gov/cancertopics/cause/radiation-risks-pediatric-CT.pdf

[34] Amis E Jr, Butler P, Applegate K, Birnbaum S, Brateman L, Hevezi J, Mettler F, Morin R, Pentecost M, Smith G. American College of radiology white paper on radiation dose in medicine. Journal of American College of Radiology, 2007:4:272-284

[35] National Cancer Institute. Interventional fluoroscopy: Reducing radiation risks for patients and staff. 2005. Available at: http://www.cancer.gov/cancertopics/interventionalfluoroscopy.

37National Cancer Institute. Interventional fluoroscopy: reducing radiation risks for patients and staff. 2005. Available at: http://www.cancer.gov/cancertopics/interventionalfluoroscopy.

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. As discussed above, this measure is appropriate for measuring quality of care in the hospital outpatient department setting. This measure also meets the consensus requirement because it is NQF-endorsed (NQF # 0510). Additionally, this measure was conditionally approved by the HQA for the hospital outpatient setting in March of 2010.

In summary, for the CY 2014 payment determination, we are proposing to retain all of the measures adopted for the CY 2013 payment determination, and to adopt six new chart-abstracted measures for the CY 2014 payment determination on the topics of diabetes care and exposure time for procedures using fluoroscopy. We are proposing that submission of the new chart-abstracted measures for the CY 2014 payment determination begin with first quarter CY 2013 discharges to be submitted in 2013. We invite public comment on this proposal for the CY 2014 payment determination.

The complete list of 30 proposed measures for the CY 2014 payment determination is shown below.

Proposed HOP QDRP Measurement Set to be Used for theCY 2014 Payment Determination
OP-1: Median Time to Fibrinolysis
OP-2: Fibrinolytic Therapy Received Within 30 Minutes
OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
OP-4: Aspirin at Arrival
OP-5: Median Time to ECG
OP-6: Timing of Antibiotic Prophylaxis
OP-7: Prophylactic Antibiotic Selection for Surgical Patients

Proposed HOP QDRP Measurement Set to be Used for theCY 2014 Payment Determination
OP-8: MRI Lumbar Spine for Low Back Pain
OP-9: Mammography Follow-up Rates
OP-10: Abdomen CT – Use of Contrast Material
OP-11: Thorax CT – Use of Contrast Material
The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data*
Preoperative Evaluation for Low Risk Non Cardiac Surgery Risk Assessment*
Use of Stress Echocardiography, SPECT MPI, and Cardiac Stress MRI post CABG*
Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)*
Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache*
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 *
Tracking Clinical Results between Visits**
Median Time from ED Arrival to ED Departure for Discharged ED Patients**
Transition Record with Specified Elements Received by Discharged Patients**
Door to Diagnostic Evaluation by a Qualified Medical Professional**
ED- Median Time to Pain Management for Long Bone Fracture **
ED- Patient Left Before Being Seen**
ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival **
Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetic Patients***
Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetic Patients***
Diabetes Mellitus: High Blood Pressure Control in Diabetic Patients***
Diabetes Mellitus: Dilated Eye Exam in Diabetic Patients***
Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients***
Exposure Time Reported for Procedures Using Fluoroscopy***

* Proposed new measure for CY 2012 payment determination

** Proposed new measure for CY 2013 payment determination

*** Proposed new measure for CY 2014 payment determination

6. Possible Quality Measures under Consideration for Future Inclusion in HOP QDRP

In previous years' rulemakings, we have provided lists of quality measures that are under consideration for future adoption into the HOP QRDP measurement set. Below is a list of measures under consideration for future rulemaking cycles.

Measures and Measurement Topics under Consideration for Future Payment Determinations Beginning with CY 2013
Measures for future development:
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.
Pneumococcal Vaccination Status
Influenza Vaccination Status
Cardiac Rehabilitation Referral
Medication Reconciliation
Appropriate surgical site hair removal
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: End of Life Care Plan
Heart Failure: Overuse of Echocardiography
Heart Failure: Post-Discharge Appointment for Heart Failure Patients

Measures and Measurement Topics under Consideration for Future Payment Determinations Beginning with CY 2013
Emergency Department Transfer Communication: Administrative Communications
Emergency Department Transfer Communication: Medication Information
Emergency Department Transfer Communication: Nursing Information
Emergency Department Transfer Communication: Patient Information
Emergency Department Transfer Communication: Physician Information
Emergency Department Transfer Communication: Procedures and Tests
Emergency Department Transfer Communication: Vital Signs
Measurement Topics for future development:
Chemotherapy
Unplanned Reintubation
Unplanned Inpatient Transfer
Post-discharge follow up
Post-discharge ED visit within 72 hours
Safe Surgery Checklist
Immunization Refusal rate
Breast cancer detection rate

We invite public comment on these quality measures and topics so that we may consider proposing to adopt them beginning with the CY 2013 payment determination. We also are seeking suggestions and rationales to support the adoption of measures and topics for the HOP QDRP which do not appear in the table above.

In addition, we are concerned about the lack of progress in reducing the rates of healthcare associated infections that was recently reported in the 2009 National Healthcare Quality Report (http://www.ahrq.gov/qual/nhqr09/nhqr09.pdf). For example, the report found that rates of postoperative sepsis increased by 8 percent. We view healthcare associated infections as a significant priority for quality measurement in order to ensure that health care does not result in avoidable harm and to inform the public about

hospitals' performance with respect to these infections. We are inviting public comment on the option to include among our prioritization criteria quality measures that assess performance on healthcare associated infections. Also, while some HOP QDRP measures cover aspects of healthcare associated infections, we are inviting suggestions on additional measures that could be added to those that hospitals would report and that we would make available to the public in order promote improvement in healthcare associated infection rates.

C. Proposed Payment Reduction for Hospitals That Fail to Meet the HOP QDRP Requirements for the CY 2011 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 for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 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. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction would apply only to the payment year involved and would 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 HOP QDRP 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 HOP QDRP 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 with comment period): "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 HOP QDRP for the CY 2010 OPD fee schedule increase factor.

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 HOP QDRP 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 hospitals' 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 HOP QDRP. 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 HOP QDRP 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. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642), we continued this policy. For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G. of this CY 2011 OPPS/ASC proposed rule.

2. Proposed Reporting Ratio Application and Associated Adjustment Policy for CY 2011

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 HOP QDRP requirements for the full CY 2011 annual payment update factor. For the CY 2011 OPPS, the proposed reporting ratio is 0.980,

calculated by dividing the reduced conversion factor of $66.930 by the full conversion factor of $68.267. We are proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. For the CY 2011 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." 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 HOP QDRP 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 HOP QDRP. 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.

D. Proposed Requirements for HOPD Quality Data Reporting for CY 2012 and Subsequent Years

In order to participate in the HOP QDRP, hospitals must meet administrative, data collection and submission, and data validation requirements (if applicable). Hospitals that do not meet the requirements of the HOP QDRP, 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 in their annual payment update factor for the applicable payment year. We established the payment determination requirements for the CY 2011 payment update in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642 through 60652).

For payment determinations affecting the CY 2012 payment update, we are proposing to implement the requirements listed below. Most of these requirements are the same as the requirements we implemented for the CY 2011 payment determination, with some proposed modifications.

1. Administrative Requirements

To participate in the HOP QDRP, we are proposing that several administrative steps be completed. These steps 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 RHQDAPU program and the HOP QDRP. From 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 HOP QDRP, 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 HOP QDRP. The hospital would be required to maintain a current QualityNet security administrator

for as long as the hospital participates in the program due to CMS information systems security requirements. 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 HOP QDRP decisions affecting the CY 2012 payment determination, hospitals that share the same CCN would be required complete a single online participation form. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we implemented an online registration form and eliminated the paper form. At this time, the participation form for the HOP QDRP is separate from the RHQDAPU 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 and also may be shared with one or more other CMS contractors that support the implementation of the HOP QDRP and be publicly reported.

We are proposing to update and retain the following deadlines, which we established in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60643), for submitting the participation form:

Hospitals with Medicare acceptance dates on or after January 1, 2011: For the CY 2012 payment update, we are proposing that any hospital that has a Medicare acceptance date on or after January 1, 2011 (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 Online System Certification and Reporting (OSCAR) 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 HOP QDRP participation allows CMS 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 invite public comment on this proposed policy.

Hospitals with Medicare acceptance dates before January 1, 2011: For the CY 2012 payment update, we are proposing that any hospital that has a Medicare acceptance date on or before December 31, 2010 that is not currently participating in the HOP QDRP and wishes to participate in the CY 2012 HOP QDRP must submit a participation form by March 31, 2011. We are proposing a deadline of March 31, 2011,

because we believe it would give hospitals sufficient time to decide whether they wish to participate in the HOP QDRP, as well as put into place the necessary staff and resources to timely report data for first quarter CY 2011 services. This requirement would apply to all hospitals whether or not the hospital billed for payment under the OPPS. We invite public comment on this proposed policy.

Under our current requirements, hospitals that want to withdraw from participation must follow the same deadlines as hospitals that want to participate. We are proposing to change this requirement. We are proposing to lengthen the time during which hospitals may withdraw from participation because we believe that hospitals should be allowed more time to consider this decision. In addition, this increased time to withdraw is comparable programmatically to our proposal under the RHQDAPU program (75 FR 23996). Specifically, for the CY 2012 payment update, we are proposing that any HOP QDRP participating hospital that wants to withdraw may do so at any time from January 1, 2011 to November 1, 2011. Hospitals that withdraw during this time period for the CY 2012 payment update would not be able to sign up to participate for the CY 2012 payment update, would have a 2.0 percentage point reduction in their CY 2012 payment update, and would be required to resubmit a participation form in order to participate for purposes of any future payment updates. We note that once a hospital has submitted a participation form, it is considered to be an active HOP QDRP participant until such time as the hospital submits a withdrawal form to CMS or the facility is designated as closed in the CMS OSCAR system. We invite public comment on this proposed policy.

2. Data Collection and Submission Requirements

a. General Data Collection and Submission Requirements

We are proposing that, to be eligible for the full CY 2012 OPPS payment update, hospitals would be required to:

- Submit data: Hospitals that would be participating in the HOP QDRP would be required to submit 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 2012 annual payment update, the applicable quarters would be as follows: 3rd quarter CY 2010, 4th quarter CY 2010, 1st quarter CY 2011, and 2nd quarter CY 2011. Hospitals that did not participate in the CY 2011 HOP QDRP, but would like to participate in the CY 2012 HOP QDRP, and that have a Medicare acceptance date on the OSCAR system before January 1, 2011, would begin data submission for 1st quarter CY 2011 services using the CY 2012 measure set that would be finalized in the CY 2011 OPPS/ASC final rule with comment period. For those hospitals with Medicare acceptance dates on or after January 1, 2011, data submission must begin with the first full quarter following the submission of a completed online participation form. For the claims-based measures, we would calculate the measures using the hospital's Medicare claims data. For the CY 2012 payment update, we would utilize paid Medicare fee-for-service (FFS) claims submitted prior to January 1, 2011, to calculate these measures. For the structural measure to be used for the CY 2012 payment determination, hospitals would be required to submit data beginning with January 1, 2011 discharges using a Web-based tool available on QualityNet beginning in 2011.

Sampling and Case Thresholds: It would not be necessary for a hospital to submit data for all eligible cases for some measures if sufficient eligible case thresholds are met. Instead, for those measures where a hospital has a sufficiently large number of cases, it would sample cases and submit data for these sampled cases rather than submitting data from all eligible cases. This sampling scheme, which includes the minimum number of cases based upon case volume, would be set out in the HOPD Specifications Manual at least three months in advance of the required data collection. We have proposed to change this notification timeframe for this sampling scheme to at least 3 months from at least 4 months to be consistent with the HOPD Specifications Manual release schedule. Hospitals would be required to meet the sampling requirements for required quality measures each reporting quarter.

In addition, in order to reduce the burden on hospitals that treat a low number of patients but otherwise meet the submission requirements for a particular quality measure, hospitals that have five or fewer claims (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 claims (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter, we are proposing that they may voluntarily do so.

Hospitals would be required submit all required data according to the data submission schedule that will be available on the QualityNet Web site (https://www.QualityNet.org). This Web site meets or exceeds all current HIPAA

requirements. Submission deadlines would, in general, be four months after the last day of each calendar quarter. Thus, for example, the submission deadline for data for services furnished during the first quarter of CY 2011 (January-March 2011) would be on or around August 1, 2011. The actual submission deadlines would be posted on the http://www.QualityNet.org Web site.

Hospitals would be required to submit 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.

Hospitals would be required to submit quality data through My QualityNet, the secure portion of the QualityNet Web site, to the OPPS Clinical Warehouse. The OPPS Clinical Warehouse, which is maintained by a CMS-designated contractor, would submit the OPPS Clinical Warehouse data to CMS. OPPS Clinical Warehouse data are not currently considered to be Quality Improvement Organization (QIO) data; rather, we consider such data to be CMS data. However, it is possible that the information in the OPPS Clinical Warehouse may at some point become QIO information. If this occurs, these data would also become protected under the stringent QIO confidentiality regulations in 42 CFR Part 480.

Hospitals would be required to collect HOP QDRP data from outpatient episodes of care to which the required measures apply. For the purposes of the HOP QDRP, an outpatient “episode of care” is defined as care provided to a patient who has not been admitted as an inpatient, but who is registered on the hospital’s medical records as an

outpatient and receives services (rather than supplies alone) directly from the hospital. Every effort would be made 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").

Hospitals would be required to submit quality data using the CCN under which the care was furnished.

To be accepted into the OPPS Clinical Warehouse, data submissions, at a minimum, would be required to 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 HOPD Specifications Manual, and must correspond to both the aggregate number of cases submitted by a hospital and the number of Medicare claims the hospital submits for payment. We are aware of "data lags" that occur when hospitals submit claims, then cancel and correct those claims; efforts would be made to take such events into account that can change the aggregate Medicare case counts. To be considered "accurate," submissions would be required to pass validation, if applicable.

We strongly recommend that hospitals review OPPS Clinical Warehouse feedback reports and the HOP QDRP 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 would be responsible for ensuring that HOP QDRP requirements are met.

Finally, during the past two years of the HOP QDRP, the submission of population and sampling data was not required, though, hospitals could submit, on a voluntary basis, the aggregate numbers of outpatient episodes of care which are eligible for submission under the HOP QDRP and sample size counts. These aggregated numbers of outpatient episodes represent the number of outpatient episodes of care in the universe of all possible cases eligible for data reporting under the HOP QDRP. For the CY 2012 payment update, we are proposing to require submission of this population and sample size data. Specifically, we are proposing that 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, hospitals would submit aggregate population and sample size counts for measure populations even if the hospital had not treated patients in a specific measure population; that is, if a hospital has not treated any patients in a specific HOP QDRP measure population, the hospital would still be required to submit a zero for its quarterly aggregate population and sample counts to meet the requirement.

We believe that hospitals have had sufficient time to become familiar with HOP QDRP data and to develop data systems necessary to support this requirement. We view it as vital for quality data reporting for hospitals to be able to determine accurately their aggregate population and appropriate sampling size data to assess their completeness of

data reporting. We rely on hospitals to properly sample cases where sampling occurs so that representative data are submitted; for hospitals to correctly sample, it is necessary for them to be able to determine their aggregate population sizes. In addition, we believe it is highly beneficial for hospitals to develop systems that can determine whether or not they have furnished services or billed for five or fewer cases for a particular measure topic on a quarterly basis.

We are proposing that the deadlines for the reporting of aggregate numbers of outpatient episodes of care and sample size counts would be the same as those for the reporting of data for the measures requiring chart abstraction, 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 CMS 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 and adherence to sampling requirements for Medicare and non-Medicare patients.

We invite public comment on these proposed requirements.

b. Extraordinary Circumstance Extension or Waiver for Reporting Quality Data

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. We are proposing to retain these procedures with some proposed modifications.

Under the process, in the event of extraordinary circumstances, such as 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 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 HOP QDRP data, 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. We are proposing to remove the requirement found in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60646) that the hospital to include an identified reason for requesting an extension or waiver in addition to the hospital's reason for requesting an extension or waiver as a requirement. We believe that this requirement is redundant and removing it will reduce unnecessary hospital burden.

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 any CY 2011 request for Extraordinary Circumstance Extension or Waiver for Reporting Quality Data requests reviews and communicate the results of these determinations within 90 days following our receipt of such a request. We are proposing to add a deadline for CMS response so that hospitals can have a designated timeline for when they should receive such a response.

This proposal would not preclude us from granting 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 these proposals.

3. HOP QDRP Validation Requirements for Chart-Abstracted Data: Data Validation Approach for CY 2012 and Subsequent Years

a. Background

In the CY 2010 OPPS/ASC proposed rule, we solicited public comments on our proposed validation methodology (74 FR 35403 through 35404). We stated that we are considering building upon what we proposed as a validation approach for CY 2012 and subsequent years by, in addition to selecting a random sample of hospitals for validation purposes, selecting targeted hospitals based on criteria designed to measure whether the data they have reported raises a concern regarding data accuracy. These possible targeting criteria included identified abnormal data patterns, whether a hospital had previously failed validation, whether a hospital had not been previously selected for validation for 2 or more consecutive years, and some combination of the some or all of the criteria.

We solicited public comments on whether such criteria, or another approach, should be applied in future years. We especially solicited suggestions for additional criteria that could be used to target hospitals for validation. We greatly appreciate all the public comments we received regarding the validation process proposed for CY 2012 and subsequent years. We responded to public comments on our proposed methodology for

CY 2012 and subsequent years but did not finalize a validation process in the CY 2010 OPPS/ASC final rule with comment period 74 FR 60650 through 60652). We noted that we would take all of the comments we received into account when we develop our validation proposals for CY 2012.

b. Proposed Data Validation Requirements for CY 2012

Similar to our proposal for the FY 2012 RHQDAPU program (75 FR 23991 through 23993), we are proposing to validate data from 800 randomly selected hospitals (approximately 20 percent of all participating HOP QDRP hospitals) each year, beginning with CY 2012 payment determination. We are proposing to sample 800 hospitals because we believe, based upon sampling simulation studies using HOP QDRP data, that sampling this number would provide a sufficient number for a representative sample of hospitals on various strata (for example, urban, rural, bed-size) while significantly reducing overall hospital burden. For CY 2012 payment determinations, we would select only from hospitals participating for the CY 2012 payment update, so if a hospital submitted data for the CY 2011, but withdrew, this hospital would not be deemed as eligible for selection. We note that because 800 hospitals would be selected randomly, every HOP QDRP-participating hospital would be eligible each year for validation selection.

For each selected hospital, we are proposing to randomly select up to a total of 48 self-reported cases from the total number of cases (12 per quarter) that the hospital successfully submitted to the OPPS Clinical Warehouse. However, if a selected hospital has submitted less than 12 cases in any quarter, only those cases available would be

validated. We believe that validating a larger number of cases per hospital, but only for 800 randomly selected hospitals, and validating these cases at the measure level (rather than the data element level) has several benefits. We are proposing up to a total of 48 cases per hospital because a sample size of about 50 is considered sufficient for detecting relationships and correlations, so a larger sample size is not deemed necessary (for reference, see Van Voohis, Wilson, Morgan, Carmen R. and Betsey L., (2007), *Understanding Power and Rules of Thumb for Determining Sample Sizes, Tutorials in Quantitative Methods for Psychology*, Volume 3(2), Pages 43 - 50). We believe that this approach is suitable for HOP QDRP data 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 selected hospital as well as at a national level; and reduce overall hospital burden because most hospitals will not be selected to undergo validation each year.

We would not be selecting cases stratified by measure or topic; our interest is whether the data submitted by hospitals accurately reflect the care delivered and documented in the medical record, not what the accuracy is by measure or whether there are differences by topic. Additionally, we note that, due to the distribution of HOP QDRP data submitted to date by hospital size, the data do not lend themselves to sampling by topic area. Specifically, small hospitals tend to have more AMI Cardiac Care cases and fewer Surgical Care cases, whereas, larger hospitals tend to have few if any AMI Cardiac Care cases and more Surgical Care cases.

Analysis of submitted HOP QDRP data indicate that this sampling design would provide sufficient case number of denominator cases per measure for determination of national and individual hospital measure estimates with acceptable levels of statistical certainty.

We are proposing to sample data for April 1, 2010 to March 31, 2011 services because this would provide a full year of the most recent data possible to use for the purpose of completing the validation in sufficient time for us to make the CY 2012 payment determinations.

A designated CMS contractor would, each quarter that applies to the validation, ask each of the 800 selected hospitals to submit medical documentation for up to 12 randomly selected cases submitted to and accepted by the HOP QDRP Clinical Warehouse. The CMS contractor would request paper copies of medical documentation corresponding to selected cases from each hospital via certified mail or other trackable method that requires a hospital representative to sign for the request letter; a trackable method would be utilized so that CMS would be assured that the hospital received the request. The hospital would have 45 calendar days from the date of the request as documented in the request letter to submit the requested documentation and have the documentation received by the CMS contractor. If the hospital does not comply within 30 calendar days of receipt of the initial medical documentation request, the CMS contractor would send a second letter by certified mail or other trackable method to the hospital, reminding the hospital that paper copies of the requested documentation must be submitted and received within 45 calendar days following the date of the initial CMS

contractor request. If the hospital does not submit the requested documentation and the documentation is not received by the CMS contractor within the 45 calendar days, then the CMS contractor would assign a "zero" score to each data element for each selected case and the case would fail for all measures in the same topic (for example, OP-6 and OP-7 measures for a Surgical Care case).

We are proposing that the letter from the designated CMS contractor would be addressed to the hospital's medical record staff identified by the hospital for the submission of records under the RHQDAPU program (that is, the hospital's medical records staff identified by the hospital to their State QIO). If CMS has evidence that the hospital received both letters requesting medical records, the hospital would be deemed responsible for not returning the requested medical record documentation and the hospital would not be allowed to submit such medical documentation as part of its reconsideration request so that information not utilized in making a payment determination is not included in any reconsideration request.

Once the CMS contractor receives the requested medical documentation, the contractor would independently reabstract the same quality measure data elements that the hospital previously abstracted and submitted, and the contractor would then compare the two sets of data to determine whether the two sets of data match. Specifically, the contractor would conduct a measures level validation by calculating each measure within a submitted case using the independently reabstracted data and then comparing this to the measure reported by the hospital; a percent agreement would then be calculated.

Specifically, the validation score for a hospital would equal the total number of measure matches divided by the total number of measures multiplied by 100 percent.

This method is the same as recommended in the CMS Hospital Value-Based Purchasing Report to Congress and is illustrated more fully on pages 83-84 of this report which can be found on our Web site at: http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf. We believe that this approach is appropriate and it was supported by many commenters when we requested comment on HOP QDRP validation requirements outlined in the CY 2010 OPPS/ASC proposed rule (74 FR 35402 through 35403; 74 FR 60647 through 60652).

To receive the full OPPS payment update, we are proposing that hospitals must attain at least a 75 percent validation score, based upon our validation process, for the designated time period. We have selected 75 percent as the threshold for the validation score because we believe this level is reasonable for hospitals to achieve while still ensuring accuracy of the data. Additionally, this level is consistent with what we proposed for the RHQDAPU program (75 FR 23993). Since we are not validating all hospital measures submitted, it is necessary to calculate a confidence interval that incorporates sampling error. We would use the upper bound of a one-tailed 95 percent confidence interval to estimate the validation score. We are proposing to use a one-tail confidence interval to calculate the validation score because it appropriately reflects our concern of whether the confidence interval for the calculated validation score includes or is above the 75 percent validation threshold for a hospital to be considered as submitting

accurate data. If the calculated upper limit is above the required 75 percent validation score threshold, we would consider a hospital's data to be 'validated" for payment purposes. The use of a one-tailed confidence interval and the 75 percent and threshold level are the same as proposed for the RHQDAPU program for FY 2012 payment determinations (75 FR 23991 through 23993).

For derivation of the upper bound of a one-tailed 95 percent confidence interval we are proposing to use a binomial distribution approach as we are looking at the percentage of measures submitted by a hospital matching what is calculated from the reabstracted data. Since the measure match rate for each hospital is a proportion, a binomial approach is appropriate, see Pagano, Robert R., (1990), *Understanding Statistics in the Behavioral Sciences*, 3rd Edition, Pages 175 - 188.

Thus, we are proposing the following formula which includes a finite population correction factor and a continuity correction factor for calculating the upper bound of the one-tailed 95 percent confidence interval:

$$\textit{Upper Confidence Limit} = p + 1.645\left(\sqrt{\frac{p(1-p)}{n}}\right)\left(\sqrt{\frac{N-n}{N-1}}\right) + \frac{1}{2n}$$

In this formula, *N* represents the population for the reporting year, *n* represents the sample size for the reporting year, *p* (calculated as a percentage) represents the validation score for the reporting year (that is, the percentage of measures matching), and 1-*p* represents the percentage of measures not matching. It should be noted that a confidence interval would not need to be calculated for hospitals that did not have enough cases to sample as the confidence interval is equal to zero (when the value of *N* is equal to *n, N*

minus *n* equals zero and the upper confidence limit is equal to the validation score in the above formula). In addition, a confidence interval would not need to be calculated for those hospitals that have a validation score, *p*, that is greater than or equal to 75 percent because the hospital has attained the minimum threshold; the upper bound of any calculated confidence interval would be 75 percent or greater.

For further information on the proposed methodology for calculation of a 95 percent confidence interval for a binomial distribution utilizing a finite population correction, see http://itl.nist.gov/div898/handbook/prc/section2/prc24.htm and http://courses.wcupa.edu/rbove/Berenson/10th%20ed%20CD-ROM%20topics/section7_3.pdf.

We solicit public comments on this proposed validation methodology.

c. Additional Data Validation Conditions under Consideration for CY 2013 and Subsequent Years

We are considering building upon what we are proposing as a validation approach for CY 2013 and subsequent years. We are 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 they have reported raises a concern regarding data accuracy. Because hospitals have gained little experience with validation under the HOP QDRP, we are considering this approach for possible use beginning with the CY 2013 payment determination. Examples of targeting criteria could include:

- Abnormal data patterns identified such as consistently high HOP QDRP 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; and/or
- Whether a hospital had any extreme outlier values for submitted data elements.

We invite 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.

E. Proposed HOP QDRP Reconsideration and Appeals Procedures

When the RHQDAPU 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 HOP QDRP and, therefore, in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), we stated our intent to implement for the HOP QDRP a reconsideration process modeled after the reconsideration process we implemented for the RHQDAPU program. In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68779), we adopted a mandatory reconsideration process that will apply 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. We are proposing to continue this process for the CY 2012

payment update with some modification. Under this proposed process, the hospitals must--

- Submit to CMS, via QualityNet, a Reconsideration Request form that would be made available on the QualityNet Web site; this form would be submitted by February 3, 2012, and would contain the following information:
  - Hospital CCN.
  - Hospital Name.
  - CMS-identified reason for failure (as provided in any CMS notification of failure to the hospital).
  - Hospital basis for requesting reconsideration. This would identify the hospital's specific reason(s) for believing it met the HOP QDRP requirements and should receive a full annual payment update.
  - 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).
  - A copy of all materials that the hospital submitted in order to receive the full payment update for CY 2012. Such material would include, but may not be limited to, the applicable Notice of Participation form or completed online registration form, and quality measure data that the hospital submitted via QualityNet.
- Submit paper copies of all the medical record documentation that it submitted for the initial validation. 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 ship this documentation on the QualityNet Web site. Final review of all mismatched data under a reconsideration request would be done by CMS.

- 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 subject to reconsideration. We would review the data elements that were labeled as mismatched as well as the written justifications provided by the hospitals, and make a decision on the reconsideration request.

For CY 2011 reconsiderations, we required that a reconsideration request must be signed by the hospital CEO (74 FR 60654). However, we have found that this requirement increases the burden for hospitals as it hampers the electronic submission of the HOP QDRP reconsideration request form. Thus, we are proposing not to include this requirement; for CY 2012 reconsiderations, reconsideration request forms would not need to be signed by the hospital's CEO.

We invite public comment on these proposed requirements.

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 CY 2012 reconsideration reviews and communicate the results of these determinations within 90 days following the deadline for submitting requests for reconsideration. In the CY 2010 OPPS/ASC final rule with comment period 74 FR 60654 through 60655), in response to a comment, we indicated that we would "complete any reconsideration reviews and communicate the results of these determinations within 60 to 90 days following the date we receive the request for reconsideration." We are proposing to refine how we describe the time frame for CY 2011 from "60 to 90 days" to within "90 days" because designating a range of dates is unnecessary for this provision.

If a hospital is dissatisfied with the result of a HOP QDRP reconsideration decision, we are proposing that the hospital may file an appeal under 42 CFR Part 405, Subpart R (PRRB appeal).

Similar to our proposal for the RHQDAPU program (75 FR 23995 through 23996), the scope of our review when a hospital requests reconsideration because it failed our validation requirement would be as follows:

- Hospital requests reconsideration for CMS contractor-abstracted data elements classified as mismatches affecting validation scores. Hospitals would be required to have timely submitted requested medical record documentation to the CMS contractor during the quarterly validation process for the requested case to be eligible to be reconsidered on the basis of mismatched data elements.

- Hospital requests reconsideration for medical records submitted during the quarterly validation process and classified as invalid record selection. Invalid record

selections would be defined as medical records submitted by hospitals during the quarterly validation process that do not match the patient's episode of care information as determined by the designated re-abstracting CMS contractor. In other words, the contractor determines that the hospital returned medical documentation that is different from that which was requested. If this designated contractor determines that the hospital submitted invalid or incorrect medical documentation, it would award a zero validation score for the case. During the reconsideration process, our review of invalid record selection would initially be limited to determining whether the medical documentation submitted initially to the designated CMS contractor was for the designated episode of care. If we determine during reconsideration that the hospital did submit medical documentation corresponding to the designated episode of care, then we would abstract data elements from the medical record documentation submitted by the hospital; otherwise, the case would not be abstracted.

- Hospital requests reconsideration for medical records not submitted to the CMS contractor within the 45 calendar day deadline. Our review would initially be limited to determining whether the CMS contractor received the requested medical record documentation within 45 calendar days, and whether the hospital received the initial medical record request and reminder notice. If we determine during reconsideration that the CMS contractor did receive the paper copy of the requested, supporting medical record documentation within 45 calendar days, then we would abstract data elements from the medical record documentation submitted by the hospital. If we determine that the hospital received two letters requesting medical documentation

and still did not submit the requested documentation within the 45 calendar day period, CMS would not accept this documentation as part of the reconsideration and CMS would not abstract data from this documentation.

In sum, we are initially limiting the scope of our reconsideration reviews involving validation to information already submitted by the hospital during the quarterly validation process, and we would not abstract submitted medical record documentation that was not submitted to the CMS contractor during the quarterly validation process. We would expand the scope of our reconsideration reviews involving validation only if we find during the initial review that the hospital correctly and timely submitted the requested medical record documentation; only then would we abstract data elements from the medical record documentation submitted by the hospital as part of our reconsideration review.

If a hospital is dissatisfied with the result of a HOP QDRP 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 these proposals.

F. Reporting of ASC Quality Data

As discussed above, section 109(b) of the MIEA-TRHCA amended section 1833(i) of the Act by redesignating clause (iv) as clause (v) and adding new clause (iv) to paragraph (2)(D) and by adding new paragraph (7). These amendments authorize the Secretary to require ASCs to submit data on quality measures and to reduce the annual

payment update in a year by 2.0 percentage points for ASCs that fail to do so. However, these provisions permit, but do not require, the Secretary to take such action.

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), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60656), we indicated that we intend to implement the provisions of section 109(b) of the MIEA-TRHCA in a future rulemaking. While promoting high quality care in the ASC setting through quality reporting is highly desirable and fully in line with our efforts under other payment systems, the transition to the revised payment system in CY 2008 posed significant challenges to ASCs, and we determined that it would be most appropriate to allow time for ASCs to gain some experience with the revised payment system before introducing other new requirements. Further, by implementing quality reporting under the OPPS prior to establishing quality reporting for ASCs, CMS would gain experience with quality measurement in the ambulatory setting in order to identify the most appropriate measures for quality reporting in ASCs prior to the introduction of the requirement for ASCs. Finally, we are sensitive to the potential burden on ASCs associated with chart abstraction and believe that adopting such measures at this time is in contrast with our desire to minimize collection burden, particularly when measures may be reported via EHRs in the future.

We continue to believe that promoting high quality care in the ASC setting through quality reporting is highly desirable and fully in line with our efforts under other payment systems. However, we continue to have the concerns outlined above for CY 2011. We intend to implement the provisions of section 109(b) of the

MIEA-TRHCA in a future rulemaking. We invite public comment on: (1) the deferral of quality data reporting for ASCs; (2) suggestions for quality measures geared toward the services provided by ASCs; and (3) potential reporting mechanisms for ASC quality data, including electronic submission of these data. In addition, we invite public comment on the following measures under future consideration for ASC quality data reporting:

- Patient Fall in the ASC;
- Patient Burn;
- Hospital Transfer/Admission;
- Wrong Site, Side, Patient, Procedure, Implant;
- Prophylactic IV Antibiotic Timing;
- Appropriate Surgical Site Hair Removal;
- Surgical site infection (SSI);
- Medication administration variance (MAV);
- Medication reconciliation; and
- VTE measures: outcome/assessment/prophylaxis.

We note that section 3006(f) of the Affordable Care Act, as added by section 10301(a) of the Affordable Care Act requires CMS to develop a plan to implement a value-based purchasing program for ASCs; this plan is due to Congress by January 1, 2011. We intend to align implementation of ASC quality reporting to be consistent with the value-based purchasing plan that will be developed. We intend to propose implementing the provisions of section 109(b) of the MIEA-TRHCA in CY 2012 rulemaking. We invite public comment on: (1) the timing of implementing quality data

reporting for ASCs; (2) suggestions for quality measures for services provided by ASCs; and (3) potential reporting mechanisms for ASC quality data, including electronic submission of these data.

G. Electronic Health Records

As we stated in the CY 2010 OPPS/ASC final rule (74 FR 60656), we are actively seeking alternatives to manual chart abstraction for the collection of quality measures for its quality data reporting programs. Among these alternatives are claims-based measure calculations, collection of data from systematic registries widely used by hospitals, and electronic submission of quality measures using EHRs. In the CY 2009, we received suggestions during the public comment period that we adopt measures that can be collected via EHRs (73 FR 68769). We agree with the commenters about the importance of actively working to move to a system of data collection based on submission from EHRs. In section XVI.B.5.b. of this proposed rule, for the CY 2014 payment determination, we are proposing to adopt several chart-abstracted quality measures for diabetes mellitus, some of which have already been specified for EHR-based capture and submission, and others that are planned for EHR-based submission in the future. We have been engaged with health IT standard-setting organizations to promote the adoption of the necessary standards regarding data capture to facilitate data collection via EHRs, and have been collaborating with such organizations on standards for a number of quality measures. We encourage hospitals to take steps toward the adoption of EHRs that will allow for reporting of clinical quality data from the EHR directly to a CMS data repository. We also encourage hospitals that are implementing, upgrading, or developing

EHR systems to ensure that such systems conform to standards adopted by HHS. We invite public comment on the future direction of EHR-based quality measurement submission.

XVII. Proposed Changes Relating to Payments to Hospitals for Direct Graduate Medical Education (GME) and Indirect Medical Education (IME) Costs

A. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and implemented in regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific, base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME for a base period by its number of residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, the period of October 1, 1983, through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the applicable PRA by the weighted number of full-time equivalent (FTE) residents working in all areas of the hospital complex (and nonhospital sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for an additional payment amount under the IPPS for hospitals that have residents in an approved GME program in order to

reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment, known as the indirect medical education (IME) adjustment, are located at 42 CFR 412.105.

The Balanced Budget Act of 1997 (Pub. L. 105–33) established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for its most recent cost reporting period ending during the 1996 calendar year. Under section 1886(d)(5)(B)(v) of the Act, a similar limit on the FTE resident count for IME purposes is effective for discharges occurring on or after October 1, 1997.

The recently enacted Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) made a number of statutory changes relating to the determination of a hospital's FTE resident count for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances. (These two pieces of legislation are collectively referred to in this document as the "Affordable Care Act.") Below we set forth our proposals to implement the provisions of the Affordable Care Act relating to Medicare direct GME and IME payments.

B. Counting Resident Time in Nonprovider Settings (Section 5504 of the Affordable Care Act)

1. Background and Changes Made by the Affordable Care Act

Effective July 1, 1987, the Social Security Act was amended to allow hospitals to count the time residents spend training in sites that are not part of the hospital (referred to as "nonprovider" or "nonhospital sites") for purposes of direct GME payments under certain conditions. Specifically, section 1886(h)(4)(E) of the Act requires that the Secretary's rules concerning the computation of FTE residents for purposes of direct GME payments "'provide that only time spent in activities relating to patient care shall be counted and that all the time so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting." (Section 1886(h)(4)(E) of the Act, as added by section 9314 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509) (OBRA 86).) Regulations implementing this provision were published in the September 29, 1989 final rule (54 FR 40292) at 42 CFR 413.86(f)(3) (now §413.78(c)), which stated that a hospital may count the time residents spend in nonprovider settings for purposes of direct GME payment if: (1) the residents spend their time in patient care activities; and (2) there is a written agreement between the hospital and the nonprovider entity stating that the hospital will incur all or substantially all of the costs of the program. The regulations at that time defined "all or substantially all" of the costs to include the residents' compensation for the time spent at

the nonprovider setting. We also interpreted section 1886(h)(4)(E) of the Act to mean that only one single hospital was permitted to incur the costs of a particular training program and count the time residents spend training in a particular nonhospital setting.

Prior to October 1, 1997, for purposes of the IME payment adjustment, hospitals were not permitted to count the time residents spent training in nonhospital settings. However, section 4621(b)(2) of the Balanced Budget Act of 1997 revised section 1886(d)(5)(B) of the Act to allow providers to count time residents spend training in nonprovider sites for IME purposes, effective for discharges occurring on or after October 1, 1997. Specifically, section 1886(d)(5)(B)(iv) of the Act was amended to provide that "all the time spent by an intern or resident in patient care activities under an approved medical residency program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all, or substantially all, of the costs for the training program in that setting." In the July 31, 1998 final rule (63 FR 41005), at §412.105(f)(1)(ii)(C) and §413.86(f)(4), we specified the requirements that a hospital must meet in order to include the time spent by residents training in a nonhospital site in its FTE count for purposes of both direct GME and IME payments (we note that §413.86(f)(4) is now redesignated as §413.78(d)). In that final rule, we also redefined "all or substantially all of the costs for the training program in the nonhospital setting" as the residents' salaries and fringe benefits (including travel and lodging where applicable), *and* the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct GME.

In order to implement section 1886(h)(4)(E) (and later, section 1886(d)(5)(B)(iv)) of the Act, and to assist contractors in determining whether a hospital incurred "all or substantially all" of the costs of the program in the nonhospital setting, we required in §413.86(f)(3) and (4) that there must be a written agreement between the hospital and the nonhospital site stating that the hospital will incur ''all or substantially all'' of the costs of training in the nonhospital setting (we note that §413.86(f)(3) and (4) is now redesignated as §413.78(c) and (d)). We later specified at §413.78(d)(2) that the written agreement must indicate the amount of compensation provided by the hospital to the nonhospital site for supervisory teaching activities.

Section 713 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) imposed a 1-year moratorium relating to certain nonhospital site teaching physician costs for the period from January 1, 2004, through December 31, 2004. During this 1-year period, we were required to allow hospitals to count FTE allopathic or osteopathic family practice residents training in nonhospital settings for IME and direct GME payment purposes without regard to the financial arrangement between the hospital and the teaching physician practicing in the nonhospital setting to which the resident was assigned. We instructed our contractors (then referred to as only "fiscal intermediaries" or "FIs") regarding the effect of section 713 of the MMA in the One-Time Notification (OTN), "Changes to the FY 2004 Graduate Medical Education (GME) Payments as Required by the Medicare Modernization Act of 2003 (MMA)" (Change Request 3071, Transmittal 61, issued on March 12, 2004). Generally, we stated in the OTN that, when settling prior year cost

reports during this 1-year period, or for family practice residents actually training in nonhospital settings during this 1-year period, contractors should allow hospitals to count allopathic and osteopathic family practice residents training in a nonhospital setting for direct GME and IME payment purposes without regard to the financial arrangement between the hospital and the nonhospital site pertaining to the teaching physicians' costs associated with the residency program. For further information on this provision and for a summary of comments and responses related to this provision, we refer readers to the FY 2005 IPPS final rule (69 FR 49176).

In an effort to respond to concerns expressed by hospitals about the administrative burden associated with meeting the written agreement requirements, in the FY 2005 IPPS final rule (69 FR 49179), at §413.78(e), we revised our regulations to allow hospitals to choose to either enter into a written agreement with the nonhospital site before the hospital may begin to count residents training at the nonhospital site, or to pay concurrently for the cost of training at the nonhospital setting. That is, in the absence of a written agreement, hospitals are required to pay "all or substantially all" of the costs of the training program in the nonhospital setting by the end of the third month following the month in which the training occurs.

On May 11, 2007, we published a final rule (72 FR 26949) that once again modified the definition of "all or substantially all of the costs for the training program in the nonhospital setting." That final rule further defined "all or substantially all" under §413.75(b) to mean at least 90 percent of the total costs of the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost

of the teaching physician's salaries attributable to direct GME. Although several public commenters had objected to our proposed redefinition of the "all or substantially all," we adopted the 90 percent rule because we believed it would substantially address concerns that had been voiced previously by the industry. With this modification, hospitals were no longer required to pay 100 percent of the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the teaching physicians' costs attributable to direct GME at the nonhospital site. This change in policy also allowed providers to use an alternative, less burdensome method to calculate the GME teaching physician costs attributable to direct GME at nonhospital sites. In addition to the redefinition of "all or substantially all of the costs," the May 11, 2007 final rule also modified the regulation text at §413.78(f)(3)(ii) to clarify that the required written agreement between a hospital and a nonhospital site must be in place before residents begin training at the nonhospital site. That final rule also specified the information that must be included in the written agreement, and stated that the amounts specified in the written agreement may be modified by June 30 of the applicable academic year.

Section 5504(a) of the Affordable Care Act made changes to section 1886 (h)(4)(E) of the Act to significantly reduce the costs that hospitals must incur for residents training in nonhospital sites in order to count the FTE residents for purposes of Medicare direct GME payments. Specifically, section 5504(a) amended the statute to allow a hospital to count all the time that a resident trains in a nonhospital site so long as the hospital incurs the costs of the residents' salaries and fringe benefits for the time that

the resident spends training in the nonhospital site. Section 5504(b) of the Affordable Care Act made similar changes to section 1886(d)(5)(iv) of the Act for IME payment purposes. For direct GME payments, the provision is effective for cost reporting periods beginning on or after July 1, 2010; for IME payments, the provision is effective for discharges occurring on or after July 1, 2010. The changes made by section 5504(a) and (b) also specify that if more than one hospital incurs the residency training costs in a nonhospital setting, those hospitals are to count a proportional share of the training time as determined by written agreement between the hospitals. In addition, section 5504(a) amended section 1886(h)(4)(E) of the Act to require hospitals to maintain documents indicating the amount of time their residents spend training in nonhospital sites relative to a base year, and to make those documents available to the Secretary.

Section 5504(c) of the Affordable Care Act specifies that the amendments made by the provisions of sections 5504(a) and (b) shall not be applied in a manner that would require the reopening of settled cost reports except where the provider has a jurisdictionally proper appeal pending on the issue of direct GME or IME payments as of March 23, 2010 (the date of the enactment of Pub. L. 111-148). We are proposing to interpret "pending, jurisdictionally proper appeal on direct GME or IME payments" to mean that in order for a hospital to request a change to its FTE count, direct GME or IME respectively, the "pending, jurisdictionally proper appeal" must be specific to direct GME or IME respectively. For example, in order for a hospital to increase its FTE count with regard to an ACA provision that is unique to IME (such as inclusion in the IME count of didactic time occurring in the hospital as specified by new section 1886(d)(5)(B)(x)(II)),

the hospital's "pending, jurisdictionally proper appeal" must be on an IME issue; IME FTEs or the available bed count. However, if the hospital's "pending, jurisdictionally proper appeal" is on an issue that only affects direct GME payments, such as the initial residency period or the Medicare patient load, that appeal would not be sufficient in order for the hospital to increase its FTE count with regard to an ACA provision that is unique to IME, such as didactic time in the hospital setting.

2. Elimination of the "All or Substantially All of the Costs for the Training Program in the Nonhospital Setting" Requirement and New Cost Requirements for Hospitals

As stated earlier, in the May 11, 2007 final rule (72 FR 26949), we redefined the phrase "all or substantially all of the costs for the training program in the nonhospital setting" under §413.75(b) of the regulations to mean at least 90 percent of the total costs of the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost of the teaching physicians' salaries attributable to nonpatient care direct GME. However, section 5504 of the Affordable Care Act revised the Act, effective on July 1, 2010, and eliminated the requirement that a hospital incur "all or substantially all of the costs for the training program in the nonhospital setting." Under the changes made by section 5504, hospitals are only required to incur the costs of the resident's salaries and fringe benefits during the time the resident spends in the nonhospital setting, and they no longer have to incur other training costs in the nonhospital site in order to count such time for direct GME and IME purposes.

We are proposing to revise our regulation at §413.75(b) accordingly to conform to these new statutory requirements. Specifically, we are proposing to revise the existing

definition of "all or substantially all of the costs for the training program in the nonhospital setting" to be effective for cost reporting periods beginning on or after July 1, 2007, and before July 1, 2010. We also are proposing to add a new §413.78(g) that details how hospitals should count residents that train in nonhospital sites for cost reporting periods beginning on or after July 1, 2010. Specifically, we are proposing to require under §413.78(g)(2) that a hospital or hospitals must incur the costs of the salaries and fringe benefits of the resident during the time the resident spends in the nonprovider setting in order to count the time spent by those residents for direct GME payment purposes. §412.105(f) has also been revised to reflect these changes for the purposes of IME payments.

3. Proposed Revision to Regulations to Allow More than One Hospital to Incur the Costs of Training Programs at Nonhospital Settings, Either Directly or Through a Third Party

As indicated above, prior to the enactment of the Affordable Care Act, we had interpreted both section 1886(h)(4)(E) of the Act (regarding direct GME) and section 1886(d)(5)(B)(iv) of the Act (regarding IME) as allowing a hospital to count the time spent by residents training in a nonhospital site only when one single hospital incurred the costs of a particular training program in a particular nonhospital setting. We noted that both sections of the statute specified that a hospital could count the time spent by residents training in a nonhospital site "if *the hospital* incurs all or substantially all of the costs for the training program in *that* setting" (emphasis added). While we understand that, in some cases, hospitals share the costs of training their respective residents in the same programs at the same nonhospital site, we have historically only allowed a hospital

to count time spent by those residents if one single hospital met the requirement to incur "all or substantially all" of the training program costs at a nonhospital site. Accordingly, two or more hospitals could not count the time spent by their residents training in a nonhospital site if they shared the training costs at the site or if a third party incurred the costs of training at a nonhospital site on behalf of several hospitals. Examples of third parties that might incur nonhospital site training program costs are a medical or dental school, or a GME administrative entity that is established to operate the GME program.

Sections 5504(a) and (b) of the Affordable Care Act specifically address the situation in which more than one hospital incurs the costs of training programs at nonhospital settings, either directly or through a third party. Sections 5504(a) and (b) amend sections 1886(h)(4)(E) and 1886(d)(5)(B)(iv) of the Act, respectively, to provide that when more than one hospital incurs these costs, either directly or through a third party, those hospitals "shall count a proportional share of the time, as determined by written agreement between the hospitals, that a resident spends training in that setting." Therefore, these statutory changes now allow hospitals to share the costs of resident training at nonhospital sites, so long as those hospitals divide the resident time proportionally pursuant to a written agreement, for the purposes of determining their respective direct GME and IME FTE resident counts at the nonhospital site. These provisions of the statute are effective for cost reporting periods beginning on or after July 1, 2010 for direct GME, and for discharges occurring on or after July 1, 2010 for IME. Accordingly, although hospitals that shared training costs at nonhospital sites could not count any of resident time spent training at those nonhospital sites prior to

July 1, 2010, hospitals can count all of that training time beginning on or after July 1, 2010, as long as they divide the resident training time proportionally.

We are proposing to revise our regulations to reflect the statutory provision that allows hospitals to proportionally share the costs of resident training at nonhospital sites under a new paragraph (g)(2) of §413.78 and to make a conforming cross-reference change under §412.105(f)(1)(ii) of the IME regulations. While the statute allows hospitals to determine by an agreement the proportional share of time that residents spend training in the nonhospital site, we are proposing that hospitals must use some reasonable basis for establishing that proportion (proposed §413.78(g)(2)(ii)). One such reasonable basis could be that each hospital counts the number of FTEs for which it incurs the salaries and fringe benefits. For example, if there are 10 FTEs training in a nonhospital setting in a particular program, and there are two hospitals that each incur the costs of the salaries and fringe benefits of 5 of those FTEs, each hospital could agree to count 50 percent of the FTEs (even if each hospital is not necessarily paying 50 percent of the cost, due to differences in resident salary amounts, this arrangement is acceptable, so long as 100 percent of the required cost is paid).

In addition to having a reasonable basis for establishing the proportion, hospitals also must be able to document the amount that they are paying collectively, and this amount must equate to *at least* the sum of all the salaries and fringe benefits of the residents for the amount of time that the residents are training in that site. The salaries and fringe benefits of the residents will vary depending upon the program year of the residents, and the specialty in which they are training. As we indicated in the

May 11, 2007 final rule (72 FR 26961), hospitals must "take into account the actual salary and fringe benefits for each FTE resident that trains in the nonhospital site, which may vary by resident." Therefore, as also indicated in the May 11, 2007 final rule (72 FR 26970), global agreements that cover a variety of issues (GME and non-GME) between the hospital(s) and nonhospital site, and that only specify a lump sum payment amount with no break out of the residents' salaries and fringe benefits, do not provide sufficient information for the Medicare contractor to determine that "all or substantially all" of the costs (or, effective July 1, 2010, that all of the residents' salaries and fringe benefits) have been paid. Accordingly, we would expect that, regardless of whether there is one hospital paying the cost, or if more than one hospital is sharing the costs, hospitals would need to determine prior to the start of nonhospital rotations (with allowance for modification by June 30 of that academic year) the total cost of the salaries and fringe benefits of the residents that are training for the proportion of the year spent in each nonhospital site. Of course, in the instance where the residents remain on the payroll of one or more hospitals for the entire year, it would be easier to document that the hospital(s) continues to pay the residents' salaries and fringe benefits when the residents rotate to nonhospital sites. Similarly, where the residents are on the payroll of the medical or dental school, or of a third party GME administrative entity, and the hospitals reimburse the school or the third party for the *entire* salary and fringe benefit costs of the residents for both hospital and nonhospital training, the hospitals could easily document that they have incurred the requisite costs of training in nonhospital sites. In some circumstances, it may be more labor-intensive for a hospital or hospitals to document that

they have incurred costs of training in the nonhospital site that equate to at least the sum of the salaries and fringe benefits of the FTE residents for the proportion of time spent in the nonhospital site. This is especially true in situations where funds are being transferred between one or more hospitals and a third party administrative entity not simply for Medicare GME purposes, but as part of global agreements that also address a variety of Medicare and non-Medicare issues. However, once the total costs for the residents' salaries and fringe benefits for time spent in the nonhospital site are determined and covered by the hospitals, the hospitals may decide among themselves the proportion of those costs each will incur, and may use a reasonable basis to allocate among themselves the proportion of FTE residents that each one will count, as discussed above.

As specified in section 5504, we are proposing further that the hospitals must record the proportion of the FTE resident time spent training in the nonhospital site that will be counted by each hospital for purposes of direct and indirect GME payment, as well as the reasonable basis for the proportion, in a written agreement between the hospitals. We are proposing to add this requirement in regulations at §413.78(g)(2)(i). If hospitals have in place written agreements with the nonhospital site in accordance with our existing regulations at §413.78(f)(3)(ii), we are proposing that the proportion of the FTE resident training time to be counted for IME and direct GME purposes by each hospital, and the basis for the proportion, may be recorded in that agreement (proposed §413.78(g)(2)(iii)). We are proposing that if the hospitals choose to pay the training program costs concurrently as described in §413.78(g)(3)(i), that is, without a written agreement, the hospitals must still agree in writing to the proportion of costs and training

time they plan to incur and count (proposed §413.78(g)(2)(iv)) in addition to the basis for that proportion, as specified by the statute. That written agreement between the hospitals must be available for CMS review and for auditing purposes. In addition, we would expect that the hospitals' records of resident training time and training costs at nonhospital sites, as required by the Affordable Care Act and as discussed below, reflect the proportions of training time and costs as agreed upon and documented in whichever type of written agreement the hospitals used to record the proportional shares of resident training time that each will count for purposes of direct GME and IME payment.

4. Proposed Changes to Regulations Regarding Recordkeeping and Comparison to a Base Year

As stated above, section 5504(a) of the Affordable Care Act requires hospitals to maintain records of the amount of time that their residents spend in nonprovider settings, and to compare that time to the time spent by their residents in nonprovider sites in a base year as the Secretary may specify. This requirement is effective for cost reporting periods beginning on or after July 1, 2010. We are proposing to incorporate this statutory requirement for maintaining records under a new paragraph (g)(5) of §413.78 of the regulations, and we anticipate amending the cost report for hospitals to include lines where hospitals can submit the required data, which is described below. These data will help CMS identify whether barriers to resident training in nonhospital sites exist. The original allowance of IME payments for training in nonhospital sights, as instituted by the BBA, was intended to act as an incentive to hospitals to increase such training. However, we have not seen a marked increase in the amount of training that occurs in nonhospital

settings in the years since the implementation of the BBA. Advocates of expanding training in nonhospital sites have alleged that CMS' rules for counting residents in nonhospital sites regarding teaching physician salary costs were an obstacle to the expansion of training in nonhospital settings. The recordkeeping and reporting requirement added by section 5504(a) of the Affordable Care Act will provide the Secretary information to assess whether nonhospital site resident training increases as a result of the statutory revision of rules that were viewed as burdensome.

We understand that rotation schedules are a primary source of information that hospitals supply to Medicare contractors for determining where and for how much time each resident spends training in each hospital or nonhospital site. Therefore, we are proposing that rotation schedules be the source for establishing the amount of time that residents spend training in nonhospital sites, both in the base year and in subsequent years. The amendment to section 1886(h)(4)(E) of the Act by section 5504(a) of the Affordable Care Act states that the Secretary shall specify the aforementioned base year for the level of training at nonhospital sites. We are proposing that cost reporting periods beginning on or after July 1, 2009 and before June 30, 2010 be the base year against which we will compare subsequent years' data to determine if the amount of nonhospital training that occurs in subsequent years increases relative to that base year (proposed new §413.78(g)(5)). We also are proposing that, to meet this documentation requirement, hospitals only need to maintain records of the total unweighted direct GME FTE count (before application of the direct GME FTE resident cap) of resident training time in nonhospital settings.

Section 5504(a) of the Affordable Care Act also made changes to require that these records be made available to the Secretary. In order for CMS to evaluate whether nonhospital site training has increased as a result of the changes made by section 5504 of the Affordable Care Act, we are proposing to include several additional cost report lines for hospitals to submit data for each of their primary care programs on a program-specific basis. With respect to hospitals' nonprimary care programs, hospitals would only need to supply that data on an overall hospital basis, and we are proposing to add one line on the cost report for hospitals to submit that data. We are only requiring program-specific data with respect to resident training time in nonhospital sites for primary care specialties because we believe that that is sufficient for the intent of this provision. The intent of this recordkeeping requirement is to see whether, as a result of the policy changes required under section 5504(a), there is an increase in the volume of residency training that takes place in nonhospital settings. Since residents at nonhospital sites typically train in primary care specialties, and in order to minimize the documentation burden on hospitals, we do not believe it is necessary to require program-specific data for other specialties that would provide only marginally useful information. For the purposes of this provision, we propose to use the definition of primary care resident in §413.75(b) to identify those programs for which we are proposing to require program-specific data.

Once this information is made available to CMS, the data would be compared to the analogous data from the base year of cost reporting periods beginning on or after July 1, 2009 and before June 30, 2010, in order for CMS to determine whether the volume of nonhospital site training has increased. Specifically, we are proposing to use

the total direct GME count of FTE training time in a primary care specialty in nonhospital sites (prior to application of direct GME FTE resident limits) as the gauge to determine if residency training time in nonhospital settings in that specialty has increased in an academic year relative to the base year. For example, if, in the base year, we find that 10.5 direct GME FTEs out of a total of 15 FTE family practice residents from a family practice residency program in a teaching hospital trained in nonhospital settings (that is, 70 percent of the FTE time of the residents in the family practice residency program was spent training in nonhospital sites), we would note the subsequent years' amount of direct GME FTE training time in nonhospital sites in that particular teaching program to see if that FTE proportion increased from 70 percent. This would help determine if more training time is spent by primary care residents in nonhospital sites. Or, for all of the nonprimary care teaching programs in a hospital, if 100 direct GME FTE residents out of 400 FTE residents spent time training in nonhospital settings (that is, 25 percent of the time spent by residents in the program is spent training in nonhospital sites), we would look to see if in subsequent years, more than 25 percent of the time spent by nonprimary care direct GME FTEs from that hospital is spent training in nonhospital sites.

C. Counting Resident Time for Didactic and Scholarly Activities and Other Activities (Section 5505 of the Affordable Care Act)

1. Background and Changes Made by the Affordable Care Act

Prior to the enactment of the Affordable Care Act, the time that residents spend training at a nonhospital setting in nonpatient care activities, as part of an approved

program, could not be included in a hospital's direct GME or IME FTE resident count. There were also differences in the rules for counting FTE resident time during the time that residents spend training in the hospital for direct GME and IME payments. For direct GME payment purposes, under 42 CFR 413.78(a), "residents in an approved program working in all areas of the hospital complex may be counted." As explained in the September 29, 1989 **Federal Register** (54 FR 40286), the hospital complex consists of the hospital and the hospital-based providers and subproviders. Therefore, the distinction between patient care activities and nonpatient care activities is not relevant to direct GME FTE count determinations when the residents are training in the hospital complex. However, for IME payment purposes, consistent with the regulations at 42 CFR 413.9 and 412.105(f)(1)(iii)(C), only time spent in patient care activities in the hospital is counted. It has been our longstanding policy that, regardless of the site of training, "we do not include residents in the IME count to the extent that the residents are not involved in furnishing patient care" (66 FR 39897, August 1, 2001).

Section 5505(a) of the Affordable Care Act added new subparagraph (J) to section 1886(h)(4) (as amended by section 5504) of the Act to allow hospitals to count certain nonpatient care activities that occur in certain nonprovider settings, including didactic conferences and seminars, in the hospital's direct GME FTE resident counts. The provision added by section 5505(a) allows a hospital to count the time that residents spend training in an approved program in a "nonprovider setting that is primarily engaged in furnishing patient care" for direct GME purposes, even if those residents are engaged in nonpatient care activities, such as didactic conferences and seminars (but not including

research not associated with the treatment or diagnosis of a particular patient), during that training time at the nonhospital site. This statutory change is effective for cost reporting periods beginning on or after July 1, 2009. We are proposing to revise our regulations at §413.78(f)(1) and (g)(1) to reflect the statutory provision.

Section 5505(b) of the Affordable Care Act addressed IME and added a new clause (x) to section 1886(d)(5)(B) of the Act which allows certain nonpatient care activities, including didactic conferences and seminars (but not including research not associated with the treatment or diagnosis of a particular patient), to be counted for IME purposes as well. However, for IME purposes, this change only applies to such activities during training that occurs in subsection (d) hospitals (which are IPPS hospitals), subsection (d) Puerto Rico hospitals (IPPS hospitals in Puerto Rico), hospitals that are reimbursed under a reimbursement system authorized under section 1814(b)(3) of the Act, or provider-based hospital outpatient departments. The IME provision is applicable to cost reporting periods beginning on or after January 1, 1983. We are proposing to revise our regulations at §412.105(f)(1)(ii)(A) through (f)(1)(ii)(D) and (f)(1)(iii)(B) to reflect these statutory provisions.

As specified in section 1886(d)(5)(B)(x)(III) of the Act, as added by section 5505(b) of the Affordable Care Act, research activities that are not associated with the treatment or diagnosis of a particular patient are excluded from the allowable IME count of FTE residents, and this specific change applies to cost reporting periods beginning on or after October 1, 2001. We discuss this provision and our proposed implementation under section XVII.C.3. of this proposed rule.

Section 10501(j) of Pub. L. 111-152 amended section 5505 of Pub. L. 111-148 to clarify the application of the provisions of section 5505. The amendment prohibits the provisions of section 5505 from being applied in a manner that would require the reopening of settled cost reports except where the provider has a jurisdictionally proper appeal pending on the issue of direct GME or IME payments as of March 23, 2010 (the date of the enactment of Pub. L. 111-148). We are proposing to reflect this provision in the proposed revisions to our regulations under §412.105(f)(1)(ii), §412.105(f)(1)(iii)(C) and §413.78(h). We are also proposing, as mentioned above with respect to Section 5504, to interpret "pending, jurisdictionally proper appeal on direct GME or IME payments" for this section to mean that in order for a hospital to request a change to its FTE count, direct GME or IME respectively, the "pending, jurisdictionally proper appeal" must be specific to direct GME or IME respectively. For example, in order for a hospital to increase its FTE count with regard to an ACA provision that is unique to IME (such as inclusion in the IME count of didactic time occurring in the hospital as specified by new section 1886(d)(5)(B)(x)(II)), the hospital's "pending, jurisdictionally proper appeal" must be on an IME issue; IME FTEs or the available bed count. However, if the hospital's "pending, jurisdictionally proper appeal" is on an issue that only affects direct GME payments, such as the initial residency period or the Medicare patient load, that appeal would not be sufficient in order for the hospital to increase its FTE count with regard to an Affordable Care Act provision that is unique to IME, such as didactic time in the hospital setting.

2. Definition of "Nonprovider Setting That is Primarily Engaged in Furnishing Patient Care"

As stated above, section 5505(a) of the Affordable Care Act amended section 1886(h)(4) of the Act to allow hospitals to count the time that residents spend in certain nonpatient care activities in nonhospital sites towards the hospitals' direct GME resident count for cost reporting periods beginning on or after July 1, 2009. The amendments made by section 5505(a) to section 1886(h)(5) of the Act include a definition of the term "nonprovider setting that is primarily engaged in furnishing patient care" to mean "a nonprovider setting in which the primary activity is the care and treatment of patients, as defined by the Secretary." In past discussions regarding our policy to disallow time spent by residents in didactic nonpatient care activities, we have given extensive explanations of what we mean by the term "patient care activities." When section 1886(h)(4)(E) of the Act was first implemented, we specifically stated that "only time spent in activities relating to patient care may be counted [in nonhospital sites]" (54 FR 40292, September 29, 1989). In 1998, when we implemented the statute allowing FTE residents to be counted in nonhospital sites for IME, we reiterated that a hospital may only count resident training time "in nonhospital sites for indirect and direct GME, respectively, if the resident is involved in patient care" (63 FR 40986, July 31, 1998). In addition, we note that the scope of the term "patient care" had been well-established in the Medicare program even prior to issuance of the first rules on counting FTE residents for purposes of direct GME and IME payments. For example, prior to the IPPS, acute care hospitals were paid by Medicare for inpatient services based on their reasonable operating costs, or

costs relating to the provision of reasonable and necessary "patient care." The longstanding regulation at 42 CFR 413.9 (Costs related to patient care) specifies that Medicare payment is limited to those services relating to "patient care," or to those relating to covered services for the care of beneficiaries. In the August 18, 2006 **Federal Register**, we defined the term "patient care activities" at 42 CFR 413.75 in a way that was consistent with these previous, plain-language applications of the term (71 FR 48142). Therefore, we currently define "patient care" at §413.75(b) as "the care and treatment of particular patients, including services for which a physician or other practitioner may bill, and orientation activities as defined in this section."

Section 5505(a) of the Affordable Care Act added a new subparagraph (K) to section 1886(h)(5) which defines the term "nonprovider setting that is primarily engaged in furnishing patient care" to mean "a nonprovider setting in which the primary activity is the care and treatment of particular patients, as defined by the Secretary." This definition uses the term "patient care" which we have defined previously, as discussed above. We are proposing to continue our current construction of the term "patient care" as described above and in current regulations and other guidance. Examples of nonprovider settings that would be "primarily engaged in furnishing patient care" are those settings in which the main mission is to provide patient care, such as doctors' offices and community health clinics. Nonprovider settings that *would not* meet these criteria include those with a main mission other than patient care. Examples of such settings are medical schools and dental schools, even if those schools are part of a larger system that includes institutions that are primarily engaged in patient care. Despite any affiliations with

patient care settings, medical and dental schools are institutions that are primarily engaged in educational activities as opposed to patient care. Medical and dental schools retain their principal mission of education regardless of their participation in various systems and affiliations, parts of which may involve settings that are primarily engaged in furnishing patient care. Another example of a nonprovider setting that does not meet the "primarily engaged in furnishing patient care" criterion set forth in this section would be a hotel or convention center. While residents may attend didactic conferences and seminars in a hotel or convention center, that didactic time cannot be counted toward a hospital's direct GME FTE count because the main mission of a hotel or convention center is the provision of hospitality and meeting services. Thus, any such time spent in a hotel or convention center would not occur in a setting that is primarily engaged in furnishing patient care.

The exclusion of medical and dental schools from the definition of "nonprovider setting that is primarily engaged in furnishing patient care" is consistent with longstanding CMS policy, and we have addressed this policy several times in the past. We explained in response to comments in the aforementioned August 18, 2006 **Federal Register** that, "[W]e understand that it is quite common for hospitals, especially large academic medical centers, to be located on the same campus as a medical school, where the buildings are very closely situated or even connected, and the facilities are often shared. However… hospitals, nonhospital sites, and medical schools are structured separately for legal and financial purposes, and are recognized independently for state licensing and Medicare cost reporting purposes. As we stated in 2006, "to put it simply,

a hospital is not a medical school, and a medical school is not a hospital" (71 FR 48093). In the August 22, 2007 **Federal Register,** we clarified that, "[T]he commenter is also correct that orientation activities in a related medical school cannot be counted. . . the nonhospital settings we were referring to in which orientation may be counted are those nonprovider settings such as physicians' offices or clinics, where patient care is routinely provided and a hospital is permitted to count the time spent by residents in accordance with our regulations at §§412.105(f)(1)(ii)(C) and 413.78(f), *not* other nonhospital settings where time spent by residents is not permitted to be counted for purposes of direct GME and IME" (72 FR 47382). Thus, while time spent by residents in certain nonpatient care activities may be counted for direct GME payment purposes in a nonhospital site primarily engaged in furnishing patient care, time spent by residents in nonpatient care activities at nonhospital sites that are *not* primarily engaged in patient care activities is not allowable for direct GME and IME payment purposes.

We are proposing to add, under §413.75, the statutory definition of "nonprovider setting that is primarily engaged in furnishing patient care" to the definition of general terms used throughout the GME regulations.

3. Distinguishing Between Allowed "Nonpatient Care Activities" and Nonallowable Research Time

As discussed above, research time that is not associated with the treatment or diagnosis of a particular patient is specifically excluded from the "nonpatient care activities, such as didactic conferences and seminars" that are otherwise allowable under section 5505 of the Affordable Care Act for the purposes of direct GME in nonhospital

sites for cost reporting periods beginning on or after July 1, 2009, and for purposes of IME in certain hospital settings for cost reporting periods beginning on or after January 1, 1983. There are several unique features of "research not associated with the treatment or diagnosis of a particular patient" that distinguish it from "nonpatient care activities, such as didactic conferences and seminars." "Research not associated with the treatment or diagnosis of a particular patient" usually comprises activities that are focused on developing new medical treatments, evaluating medical treatments for efficacy or safety, or elaborating upon knowledge that will contribute to the development and evaluation of new medical treatments in the future, rather than on establishing a diagnosis or furnishing therapeutic services for a particular patient.

Section 5505 further distinguishes "research not associated with the treatment or diagnosis of a particular patient" from "nonpatient care activities, such as didactic conferences and seminars," by specifying that nonpatient care activities include "didactic conferences and seminars." Conferences or seminars could include an administrative rotation, which would include resident training in the administrative aspects of medical care such as practice management.

4. Approved Leaves of Absence

In the FY 2008 IPPS proposed rule (72 FR 24814), we proposed to remove vacation, sick leave and other types of leave from the FTE calculation for IME and for direct GME purposes. We proposed this policy based on our belief that such leave time involved neither patient care nor nonpatient care activities. However, we did not finalize this proposed policy after many public commenters explained that the implementation of

the policy would involve significant administrative burdens (FY 2008 IPPS final rule, 72 FR 47374). Thus, we did not revise our previously existing policy which allowed vacation and sick leave generally to be counted for direct GME and IME purposes. In the FY 2008 IPPS proposed rule, we also proposed to continue to count the time spent by residents in orientation activities in both the hospital and nonhospital settings. We proposed this policy because we recognized the distinct character of orientation activities as essential to the provision of patient care by residents. We did finalize our policy on orientation time, and in doing so, we specified that *patient care activities* means the care and treatment of particular patients, including services for which a physician or other practitioner may bill, and orientation activities (§413.75(b)), effective for cost reporting periods beginning on or after October 1 2007.

Section 5505(a) of the Affordable Care Act added new subparagraph (K) to section 1886(h)(4) to clarify that hospitals may count residents' vacation, sick leave, and other approved leave time toward the hospitals' direct GME FTE resident count, so long as the leave does not prolong the total time the resident participates in his or her approved program. This direct GME provision regarding leave time is effective for cost reporting periods beginning on or after January 1, 1983. In addition, section 5505(b) of the Affordable Care Act allows hospitals to count residents' vacation, sick leave, and other approved leave time toward the hospitals' IME FTE resident count, as long as the leave does not prolong the total time the resident participates in his or her approved program. This IME provision regarding leave time is effective for cost reporting periods beginning on or after January 1, 1983.

We are proposing to revise our regulations to reflect these statutory changes regarding counting residents' vacation, sick leave, and other approved leave time toward the hospitals' direct FTE resident count under new §413.78(h) for GME and under §412.105(f)(1)(iii)(D) for IME. Please note that each hospital is to count the proportion of the leave of absence time as specified in 72 FR 47382. There, we explained that regardless of which hospital is paying the resident's salaries and fringe benefits, the hospital to which the resident is assigned during the time the vacation is taken is the hospital that counts that FTE time for direct GME and IME. If the rotation schedule does not clearly indicate where the resident is assigned during the time the vacation is taken, the hospitals to which the resident rotates over the course of the academic year would divide and count the resident's vacation time proportionately based on the amount of time spent in actual training at the respective hospitals. We are also proposing to specify that "other approved leave" includes those types of generally accepted leave of short duration (those that do not prolong the total time that the resident is participating in the approved training program) that have not been included in our resident leave time policies in the past. Examples of such "other approved leave" could include jury duty, other court leave, or voting leave.

D. Reductions and Increases to Hospitals' FTE Resident Caps for GME Payment Purposes (§§412.105(f)(1)(iv) and 413.79(m) and (o))

1. General Background on Methodology for Determining the FTE Resident Count

As we discuss in section XVII.A. of this proposed rule, Medicare makes both direct and indirect GME payments to hospitals that train residents in approved medical

residency training programs. Direct GME payments are made in accordance with section 1886(h) of the Act, based generally on hospital-specific PRAs, the number of FTE residents, and the hospital's Medicare patient share. IME payments are made in accordance with section 1886(d)(5)(B) of the Act, based generally on the ratio of the hospital's FTE residents to the number of hospital beds. Accordingly, the calculation of both direct GME and IME payments is affected by the number of FTE residents that a hospital is allowed to count; generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress instituted a cap on the number of allopathic and osteopathic residents a hospital is allowed to count for direct GME and IME purposes under the provisions of section 1886(h)(4)(F) of the Act for direct GME and section 1886(d)(5)(B)(v) of the Act for IME. Dental and podiatric residents are not included in this statutorily mandated cap.

2. Reduction of Hospitals' FTE Resident Caps under the Provisions of Section 5503 of the Affordable Care Act

Medicare makes direct GME and IME payments based on the number of FTE residents the hospital is permitted to count, as limited by the hospital's FTE resident caps. Some hospitals have trained a number of allopathic and osteopathic residents in excess of their FTE resident caps. Other hospitals have reduced their FTE resident counts to some level below their FTE resident caps. Section 5503 of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for reductions in the statutory FTE resident

caps for direct GME under Medicare for certain hospitals, and authorizes a "redistribution" to other hospitals of the estimated number of FTE resident slots resulting from the reductions. Section 5503 also amended section 1886(d)(5)(B)(v) to require application of the provisions of 1886(h)(8) "in the same manner" to the FTE resident caps for IME. A previous redistribution of "unused" FTE resident slots was performed under section 422 of Pub. L. 108-173 (the Medicare Modernization Act of 2003). Section 422 provided for the redistribution of unused residency positions effective for portions of cost reporting periods beginning on or after July 1, 2005. While section 5503 of the Affordable Care Act is similar to section 422 of Pub. L. 108-173, there are substantive differences between the two provisions.

The new section 1886(h)(8)(A) of the Act provides that, effective July 1, 2011, a hospital's FTE resident cap will be reduced if its "reference resident level," is less than its "otherwise applicable resident limit," as these terms are described below. Rural hospitals with fewer than 250 acute care inpatient beds as well as those hospitals described in section XVII.D.5. of this proposed rule are exempt from a reduction. For other hospitals, any such reduction will be equal to 65 percent of the difference between the hospital's "otherwise applicable resident limit" and its "reference resident level."

Under the new section 1886(h)(8)(B) of the Act, the Secretary is authorized to increase the FTE resident caps for certain categories of hospitals for portions of cost reporting periods occurring on or after July 1, 2011, by an aggregate number that does not exceed the estimated overall reduction in FTE resident caps for all hospitals under section 1886(h)(8)(A) of the Act. A single hospital may receive an increase in its FTE

resident cap of no more than 75 additional FTEs. That is, a hospital would be allowed to receive up to 75 additional slots for direct GME and up to 75 additional slots for IME. In determining which hospitals would receive an increase in their FTE resident caps, section 1886(h)(8)(B) of the Act directs us to--

- Take into account the demonstrated likelihood of the hospital filling the additional positions within the first three cost reporting periods beginning on or after July 1, 2011.

- Take into account whether the hospital has an accredited rural training track program.

- Distribute 70 percent of the resident slots to hospitals located in States with resident-to-population ratios in the lowest quartile.

- Distribute 30 percent of the resident slots to hospitals located in a State, a territory of the United States, or the District of Columbia that are among the top 10 States, territories, or Districts in terms of the ratio of the total population living in an area designated as a health professional shortage area (HSPA), as of March 23, 2010, to the total population, and to hospitals located in rural areas.

In summary, section 5503 of the Affordable Care Act added a new section 1886(h)(8) of the Act that prescribes a methodology for determining reductions to certain hospitals' FTE resident caps based on unused FTE resident slots, provides for certain exceptions to the FTE resident cap reductions, and includes general criteria that CMS must consider in making a "redistribution" to other hospitals of the estimated number of FTE resident slots resulting from the reductions in the FTE resident caps. In this

proposed rule, we are proposing procedures for determining whether, and by what amount, a hospital's FTE resident cap is subject to a reduction under section 1886(h)(8)(A) of the Act. We also are specifying an application process for hospitals that seek to receive increases in their FTE resident caps and the specific criteria that we will use to determine which hospitals will receive increases in their FTE resident caps under section 1886(h)(8)(B) of the Act.

3. Hospitals Subject to the FTE Resident Cap Reduction

As indicated earlier, section 1886(h)(8)(A) of the Act, as added by section 5503 of the Affordable Care Act, provides that if a hospital's "reference resident level" is less than its "otherwise applicable resident limit," its FTE resident cap(s) will be reduced by 65 percent of the difference between its "otherwise applicable resident limit" and its "reference resident level." Under section 1886(h)(8)(H)(i) (as added by section 5503 of the Affordable Care Act), the "reference resident level" refers to the number of unweighted allopathic and osteopathic FTE residents who are training at a hospital in a given cost reporting period. That is, the "reference resident level" refers to a hospital's allopathic and osteopathic FTE resident count for a specific period. Under section 1886(h)(8)(H)(ii) the "otherwise applicable resident limit" refers to a hospital's FTE resident cap established under sections 1886(h)(4)(F)(i) and (h)(4)(H) of the Act for direct GME payment purposes and a hospital's resident cap established under section 1886(d)(5)(B)(v) for IME payment purposes. For most hospitals, the permanent FTE cap under section 1886(h)(4)(F)(i) of the Act is based on: (1) for an urban hospital, the number of unweighted allopathic and osteopathic FTE residents in the hospital's most

recent cost reporting period ending on or before December 31, 1996 (the "1996 cap"); (2) for a rural hospital, 130 percent of the 1996 cap, adjusted as specified under existing §413.79(c)(2); and (3) any adjustments to the hospital's cap under paragraph (7), which specifies the previous "redistribution" of resident positions required by section 422 of Pub. L. 108-173. Section 1886(h)(4)(H) of the Act specifies that a hospital's FTE resident cap under subparagraph (F) may be adjusted for a new medical residency training program established on or after January 1, 1995, participation in a Medicare GME affiliated group, and establishment by an urban hospital of a separately accredited rural training track program. We are proposing that, in defining a hospital's "otherwise applicable resident limit" for purposes of section 1886(h)(8)(A) of the Act, we will look at the hospital's 1996 cap during its reference year, as adjusted for the following criteria: new programs as defined at §413.79(e); participation in a Medicare GME affiliation agreement as defined at §§413.75(b) and 413.79(f); participation in an Emergency Medicare GME affiliation agreement as defined at §413.79(f); participation in a hospital merger; and whether an urban hospital has a separately accredited rural training track program as defined at §413.79(k). We discuss the applicability of Medicare GME affiliation agreements under section 1886(h)(8)(A) of the Act in more detail under section XVII.D.8.c. of this proposed rule and the treatment of hospital mergers under section XVII.D.8.d. of this proposed rule. Furthermore, section 1886(h)(8)(H)(iii) of the Act requires that, in determining a hospital's "otherwise applicable resident limit," section 1886(h)(7)(A) of the Act shall be taken into account. Section 1886(h)(7)(A) of the Act refers to the reduction to a hospital's cap(s) under section 422 of Pub. L. 108–173. The

application of section 422 of Pub. L. 108–173 to the implementation of section 5503 of the Affordable Care Act is further discussed under section XVII.D.10. of this proposed rule.

In our discussion of the provisions of section 5503 of the Affordable Care Act under this section of this proposed rule, we generally refer to a hospital's number of unweighted allopathic and osteopathic FTE residents in a particular period as a hospital's "resident level." We also refer to a hospital's resident level in the applicable "reference period," as explained further below, as the hospital's "reference resident level." In addition, we refer to the "otherwise applicable resident limit" as the hospital's FTE resident cap that is applicable during the relevant cost reporting period. Thus, we are proposing, effective for portions of cost reporting periods beginning on or after July 1, 2011, we will permanently reduce the hospital's FTE resident cap by 65 percent of the difference between the reference resident level and the hospital's otherwise applicable resident limit for IME and direct GME respectively. For example, if a hospital's otherwise applicable resident limit for the reference period is 100, and its reference resident level is 80 FTEs, we will reduce the hospital's FTE resident cap by 13 FTEs [0.65 (100 – 80)] = 13. We are proposing to add new regulations at §412.105(f)(1)(iv)(B)(*2)* for IME and at §413.79(m) for direct GME to reflect our proposals regarding reductions to hospitals' FTE resident caps under section 5503.

4. Exemption from FTE Resident Cap Reduction for Certain Rural Hospitals

Section 1886(h)(8)(A)(ii)(I) of the Act, as added by section 5503 of the Affordable Care Act, specifically exempts rural hospitals (as defined in

section 1886(d)(2)(D)(ii) of the Act) with fewer than 250 acute care inpatient beds from reductions to their FTE resident caps under section 1886(h)(8)(A). Section 1886(d)(2)(D)(ii) of the Act defines a rural area as any area outside a Metropolitan Statistical Area (MSA). Under the existing regulations at §412.62(f)(ii), an "urban area" means: (1) an MSA or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or (2) the following New England counties: Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island. Under existing §412.62(f)(iii), a "rural area" means any area outside an urban area. We note that we no longer use the term MSA, and instead use the term Core-Based Statistical Area (CBSA) for locality and wage index purposes. A hospital's bed size is based on its number of available beds, as determined for IME payment purposes under §412.105(b) of the regulations. For purposes of determining whether a rural hospital has fewer than 250 beds, we are proposing to use data from the rural hospital's most recent cost reporting period ending on or before March 23, 2010. (This information may be found on Worksheet S-3, Part I of the Medicare cost report, CMS-2552-96, the sum of lines 1 and 6 through 10 in column 2, minus line 26 in column 6, divided by the number of days in the cost reporting period.) We are proposing that if a rural hospital has fewer than 250 beds in its most recent cost reporting period ending on or before March 23, 2010, the hospital would not be subject to a possible reduction to its FTE resident cap(s) under section 1886(h)(8)(A) of the Act. However, if a rural hospital has at least 250 beds in its

most recent cost reporting period ending on or before March 23, 2010, we are proposing that the rural hospital would be subject to a reduction to its FTE resident cap(s).

5. Application of Section 5503 to Hospitals That Participate in Demonstration Projects or Voluntary Residency Reduction Programs and Certain Other Hospitals

In addition to certain rural hospitals as noted above, section 1886(h)(8)(A)(ii) of the Act also exempts certain other hospitals from a cap reduction.

Section 1886(h)(8)(A)(ii)(II) of the Act, as amended by section 5503 of the Affordable Care Act, specifically exempts "a hospital that was part of a qualifying entity which had a voluntary residency reduction plan approved under paragraph (6)(B) or under the authority of section 402 of Public Law 90-248, if the hospital demonstrates to the Secretary that it has a specific plan in place for filling the unused positions by not later than 2 years after the date of enactment of this paragraph." This language is referring to the National Voluntary Residency Reduction Plan (VRRP), the New York Medicare GME Demonstration (New York Demonstration), and the Utah Medicare GME Demonstration (Utah Demonstration).

In July 1997, 42 New York teaching hospitals participated in the New York Demonstration. An additional seven hospitals joined the New York Demonstration in July 1998. The purpose of the New York Demonstration was to test reimbursement changes associated with residency training to determine whether hospitals could use time-limited transition funding to replace and reengineer the services provided by a portion of their residency trainees. In exchange for reducing its count of residents by 20 to 25 percent over a 5-year period, while maintaining or increasing its primary

care-to-specialty ratio of residents, a participating hospital (or consortium of hospitals) participating in the New York Demonstration would receive "hold harmless payments" for 6 years.

Since 2003, nine Utah teaching hospitals have participated in the Utah Demonstration to allocate Medicare GME funding to Utah hospitals based on health professions workforce planning. Under the Utah Demonstration, Medicare contractors redirect Medicare direct GME funds from each of the teaching hospitals in Utah and pay those amounts to the Utah Medical Education Council, an agency of the State government.

Under the VRRP approved under section 1886(h)(6)(B) of the Act, hospitals could use time-limited transition funding to replace the services provided by a portion of their residents. In exchange for reducing its count of residents by 20 to 25 percent over a 5-year period, while maintaining or increasing its primary care-to-specialty ratio of residents, a VRRP participating hospital would receive "hold harmless payments" for 5 years.

Based on the language of section 1886(h)(8)(A)(ii)(II) of the Act, we are proposing that hospitals that participated in the New York Demonstration, the Utah Demonstration, or a VRRP could be exempt from a cap reduction under section 1886(h)(8)(A) of the Act. We are proposing to not differentiate between those hospitals that withdrew from either demonstration prior to its completion and those hospitals that completed either demonstration. That is, we are proposing that any hospital that, at some point, participated in the New York Demonstration, the Utah Demonstration, or the

VRRP could be exempt from a cap reduction. Specifically, consistent with the statutory language at section 1886(h)(8) of the Act, even though only seven hospitals actually completed the New York Demonstration, any hospital that participated in the New York Demonstration could be exempt from a cap reduction. As required under section 1886(h)(8)(A)(ii)(II) of the Act, to be exempt from the cap reduction, hospitals that had a VRRP approved under section 1886(h)(6)(B) of the Act or hospitals that participated in a demonstration project approved under section 402 of Pub. L. 90-248 must demonstrate to the Secretary that they have a plan in place for filling their unused slots within 2 years after the date of enactment of Pub. L. 111-148 (that is, by March 23, 2012). We are proposing that these hospitals must submit their plans specifying how they would fill their unused slots to CMS by December 1, 2010, in order to be exempt from a cap reduction.

In addition to the hospitals described under 1886(h)(8)(A)(ii)(II) of the Act, section 1886(h)(8)(A)(ii)(III) of the Act exempts a hospital described under section 1886(h)(4)(H)(v) of the Act from a cap reduction. Therefore, we are proposing that such hospital described under section 1886(h)(4)(H)(v) of the Act be exempt from a cap reduction.

Finally, section 1886(h)(8)(H)(i) of the Act provides that the hospital's reference resident level is the resident level for the one cost reporting period out of the three most recent cost reporting periods ending before March 23, 2010 with the highest resident level. Under section 1886(h)(8)(A)(i), that reference resident level is used to make the determination of whether a hospital's FTE resident cap(s) should be reduced. Therefore,

we are proposing that if a hospital trains at or above its otherwise applicable resident level in all of its three most recent cost reporting periods ending before March 23, 2010, the hospital would be exempt from a cap reduction. A separate determination would be made regarding any reduction to the hospital's direct GME cap and its IME cap.

6. Determining the Estimated Number of FTE Resident Slots Available for Redistribution

In accordance with section 1886(h)(8)(A) of the Act, as added by section 5503 of the Affordable Care Act, we will determine the number of resident positions available for redistribution by estimating the expected reductions to hospitals' FTE resident caps. We believe that section 1886(h)(8)(A) of the Act allows us to distinguish between the FTE counts that are used to determine the number of FTE resident slots that are available for redistribution (that is, the "redistribution pool") and the actual number of FTE residents by which hospitals' FTE resident caps are ultimately reduced. We are proposing to estimate the reduction to a hospital's FTE cap under section 1886(h)(8)(A) of the Act for purposes of determining the number of FTEs that a hospital might contribute to the redistribution pool. We are proposing to estimate the redistribution pool for redistribution in accordance with section 1886(h)(8)(B)(i) of the Act, as added by section 5503(a)(4), which states: "The aggregate number of increases in the otherwise applicable resident limit under this subparagraph shall be equal to the aggregate reduction in such limits attributable to subparagraph (A) (as estimated by the Secretary)" (emphasis added). Therefore, we are proposing to estimate and redistribute the number of resident slots in the redistribution pool, and to ensure that the aggregate number of FTE residents by

which we increase the FTE resident caps of qualifying hospitals under section 1886(h)(8)(B) of the Act is not more than CMS' estimate of the redistribution pool. We note if we were subsequently to perform an audit, as described further in section XVII.D.7. of this proposed rule, in order to make a final determination regarding any reductions to a hospital's FTE resident cap, and find that the aggregate number of FTE resident reductions differed from the number CMS had initially estimated for the redistribution pool, the number of slots that can be redistributed from the redistribution pool to qualifying hospitals would not be affected.

To ensure that we will begin making payments for most hospitals based on the revised FTE resident caps by July 1, 2011, we are proposing to set a date by which we will have determined a hospital's reference resident level and compared it to the hospital's otherwise applicable FTE resident cap(s) to estimate whether, and by how much, the hospital's FTE cap(s) would be reduced. We are proposing that this date be May 1, 2011, and that date would apply for all hospitals for purposes of determining an estimate of whether and by how much their FTE resident caps should be reduced. In the event that the Medicare contractors have not completed an audit (explained further under section XVII.D.7. of this proposed rule) by May 1, 2011, we are proposing to estimate by May 1, 2011, the number of FTE residents by which a hospital's FTE resident cap is expected to be reduced. For example, a Medicare contractor may estimate by May 1, 2011, that Hospital A's FTE resident cap should be reduced by 10 FTEs. Thus, we would place 10 FTEs into the redistribution pool. It is possible that even after May 1, 2011, the contractor may continue to audit Hospital A's relevant cost reports to

determine if, in fact, 10 FTEs is the appropriate number by which to reduce Hospital A's FTE resident cap, and could ultimately conclude that Hospital A's FTE resident cap should only be reduced by 8 FTEs. If the Medicare contractor does not make this revised determination based on the audit by May 1, 2011, we would reduce Hospital A's FTE resident cap by 8 FTEs effective July 1, 2011, but the number of FTE residents in the redistribution pool attributable to Hospital A would remain at 10 FTEs (the estimated number as of May 1, 2011). Similarly, if the Medicare contractor ultimately concluded that Hospital A's FTE resident cap should be reduced by 12 FTEs, but this final determination is not made by May 1, 2011, Hospital A's FTE resident cap would be reduced by 12 FTEs effective July 1, 2011, but the number of FTE residents in the redistribution pool attributable to Hospital A would remain at 10 FTEs. Therefore, because we believe that section 1886(h)(8)(B)(i) of the Act allows us to distinguish between the FTE counts that are used to determine the size of the redistribution pool, and the actual aggregate number of FTE residents by which hospitals' FTE resident caps are ultimately reduced, we are proposing, to use estimated information to determine possible reductions to hospitals' FTE resident caps to estimate the number of FTE resident slots to be distributed under section 1886(h)(8)(B). In addition, we note that, as was done when we implemented section 422 of Pub. L. 108-173, Medicare contractors will provide hospitals with a time-limited opportunity to review cap reduction determinations for possible technical errors before they are finalized.

7. Reference Cost Reports That Are Under Appeal

We understand that there may be instances where a hospital's otherwise applicable resident limit or a hospital's FTE resident count for a reference cost reporting period might be under appeal. When implementing section 422 of Pub. L. 108-173, we stated in the August 11, 2004 **Federal Register** (69 FR 49118) that we believe that it is in the best interest of the Medicare program, CMS, the contractors, and the hospitals to adopt an approach that allows for finality as early as possible during the process of implementing this provision. We stated that we believed Congress gave some consideration to the challenges we would encounter in implementing a provision as complex as section 422 in such a short timeframe by providing the Secretary with the discretion to distinguish between the FTE counts that are used to estimate the number of FTE resident slots that are available for redistribution (that is, the "redistribution pool"), and the actual number of FTE residents by which hospitals' FTE resident caps are ultimately reduced.

Furthermore, as we stated in the August 11, 2004 **Federal Register** (69 FR 49118), the fact that the Congress took the unusual step of including the language at section 1886(h)(7)(D) of the Act which provides that, "There shall be no administrative or judicial review . . . with respect to determinations made under this paragraph," supports the position advocating for finality. If we had delayed determinations concerning hospital-specific FTE cap determinations until all affected cost reports are settled, audited, and appealed through the various channels normally available to providers, the language, and in particular the specified timeframe, under section

1886(h)(7)(D) of the Act would have been rendered meaningless. Therefore, despite the complexity of section 422 and the potential for profound and long-term GME payment ramifications, we believed that the Congress did not expect the implementation of section 422 provision to linger indefinitely. Rather, by limiting appeal rights and requiring an effective date of July 1, 2005 for reductions in FTE resident caps (which required implementation in a relatively short timeframe), the Congress expected section 1886(h)(7) of the Act, as added by section 422 of Pub. L. 108-173, to be implemented with expediency and finality.

Similarly, in implementing section 5503 of the Affordable Care Act, we note that determinations under section 1886(h)(8)(A)(i) of the Act are required to be made effective July 1, 2011, and, for the same reasons cited when we implemented section 422, we believe these determinations should be final on, or as quickly as possible after, that date. We note that section 5503(a)(3) of the Affordable Care Act modified section 1886(h)(7)(E) of the Act by inserting "or paragraph (8)" to specify that there shall be no administrative or judicial review with respect to determinations made under section 5503 as well. Therefore, as was our final policy when implementing section 422, we are proposing to not wait for appeals of reference period cost reports to be resolved before making a final determination as to whether and by how much a hospital's FTE resident cap will be reduced. However, we do perceive the need in certain instances to continue audit work for a limited time period past July 1, 2011, to promote the accuracy of FTE resident cap determinations. As under section 422, we are proposing to adopt a policy that would require the Medicare contractors to use the latest available cost report or audit

data at the time they make their determinations. If, as of the time the Medicare contractor makes the determination as to whether and by how much a hospital's FTE resident cap should be reduced, there is a pending appeal of the hospital's otherwise applicable resident limit for the reference cost reporting period (that is, a final decision has not been rendered), the Medicare contractor would not wait until a decision is rendered, but would use the FTE resident cap from the initially settled (as indicated in the Notice of Program Reimbursement (NPR)) reference period cost report. Alternatively, if the appeal regarding the otherwise applicable resident limit has been resolved as of the time that the Medicare contractor makes the determination as to whether and by how much a hospital's FTE resident cap should be reduced, the Medicare contractor would use the FTE resident level that will be used in issuing the subsequent NPR, as established through the appeal. If a reference period cost report has been submitted but not settled at the time the Medicare contractor is making the determination as to whether and by how much a hospital's FTE resident cap should be reduced, the reference resident level is subject to audit by the Medicare contractor, and the final determination regarding any possible reduction to the hospital's FTE resident cap is not subject to appeal. Although we would make every effort to provide contractors with the resources they need to complete as many audits as possible in time to notify each hospital by July 1, 2011, of their FTE cap determinations under section 1886(h)(8)(A) of the Act, there may be instances where the audits of the reference resident levels may not be completed by July 1, 2011. We anticipate that within the scope of their normal audit work, the Medicare contractors will complete as many of these audits as possible, and some of the audits may not be

completed until December 31, 2011. We are proposing that, in accordance with section 1886(h)(8)(A) all cap determinations made after July 1, 2011 and through December 2011 will be effective retroactively to July 1, 2011.

8. Determining the Possible Reduction to a Hospital's FTE Resident Cap

a. Reference Resident Level--General

In order to determine if a hospital's reference resident level is less than the hospital's otherwise applicable FTE resident cap, section 1886(h)(8)(H) of the Act, as added by section 5503 of the Affordable Care Act, directs the Secretary to use one of three reference cost reporting periods. Section 1886(h)(8)(H) of the Act directs the Secretary to use a hospital's most recent cost reporting period ending before the date of enactment, which is March 23, 2010, with the highest resident level "for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary," as the reference period. Generally, if the hospital's resident level for either direct GME or IME is less than the hospital's otherwise applicable resident limit for direct GME or IME, respectively, in the reference period, the hospital's FTE resident cap for direct GME and/or IME will be reduced by 65 percent of the difference between the resident level and the otherwise applicable resident limit. We note that, for purposes of determining a reduction to a hospital's direct GME cap, the unweighted direct GME cap will be compared to the direct GME FTE resident count. The following explanation is an example of how a hospital's cap(s) would be reduced under section 1886(h)(8)(A) of the Act. For purposes of this example, Hospital A's three most recent cost reporting periods ending before March 23, 2010, which have been submitted to the Medicare contractor are

as follows: July 1, 2006 – June 30, 2007; July 1, 2007 – June 30, 2008; and July 1, 2008 – June 30, 2009. Hospital A's FTE resident count and FTE resident caps (as adjusted for those items discussed in section XVII.D.3. of this proposed rule) are as noted in the table.

Cost Reporting Period	IME Unweighted FTE Count	Direct GME Unweighted FTE Count	IME FTE Cap	Direct GME Cap
July 1, 2006 – June 30, 2007	17	20	18	20
July 1, 2007 – June 30, 2008	16	21	20	20
July 1, 2008 – June 30, 20099	14	20	20	20

As noted earlier in this preamble, a separate determination regarding whether and by how much to reduce a hospital's cap will be made for its direct GME cap and for its IME cap. In order to determine whether Hospital A would be subject to a cap reduction, we must first determine whether Hospital A was training at or above its cap in all three most recent (settled or submitted) cost reporting periods ending before March 23, 2010. For purposes of a reduction to Hospital A's IME cap, we note from the chart above that in all three cost reporting periods, Hospital A is training below its otherwise applicable resident limit for IME. Therefore, we know that Hospital A would be subject to an IME cap reduction. In order to determine which cost reporting period should be used as the reference period to determine the FTE cap reduction, we would use the cost reporting period with the highest FTE resident count for IME, which would be July 1, 2006 - June 30, 2007. Therefore, we calculate the difference between the otherwise applicable resident limit for IME for the reference period (July 1, 2006 - June 30, 2007) and the reference resident level for IME, and determine the IME cap reduction based on 65 percent of the difference. For purposes of Hospital A's IME cap reduction, we would determine the difference between 18 (the otherwise

applicable resident limit) and 17 (the reference resident level) and multiply that difference by 65 percent [(18-17) x .65] = 0.65. Therefore, the IME FTE cap for Hospital A would be reduced by 0.65 of an FTE. For purposes of a reduction to Hospital A's direct GME cap, we note from the chart above that Hospital A was training at or above its otherwise applicable resident limits for direct GME in all three cost reporting periods. Because a hospital that is training at or above its cap in all three cost reporting periods is exempt from a cap reduction, we would conclude that Hospital A's direct GME cap would not be reduced for direct GME payment purposes. We note that, in general, if a hospital was not participating in a Medicare GME affiliated group during any of its three most recent cost reporting periods ending before March 23, 2010, its reference cost reporting period will be the cost reporting period with the least amount of difference between the reference resident level and the otherwise applicable resident limit. In addition, we are proposing, that if a hospital has the same resident level for two or more cost reporting periods and that resident level is the "highest" resident level, we will use the cost reporting period of those "highest" cost reporting periods in which there is the least amount of difference between the resident level and the otherwise applicable resident limit to determine a cap reduction.

b. Audits of the Reference Cost Reporting Periods

As mentioned under XVII.D.8.a. of this proposed rule, to determine a possible reduction to a hospital's FTE resident cap, section 1886(h)(8)(H)(i) of the Act, as added by section 5503(a) of Affordable Care Act, directs the Secretary to use, as the reference cost report, the one cost report out of the hospital's three most recent cost reporting

periods ending before March 23, 2010, with the highest resident count "for which a cost report has been settled (or, if not, submitted (subject to audit), as determined by the Secretary" (emphasis added). We are proposing that if a hospital's cost report for the reference cost reporting period has been settled, the hospital's settled cost report, without further audit, would be used to determine possible reductions to the FTE resident caps. We note that the "settled" cost report does not necessarily mean the initial cost report settlement. The Medicare contractor may have previously settled the cost report, reopened it to audit it, and then settled the cost report again, issuing a revised NPR. Thus, we would refer to the more recently issued NPR for that cost reporting period. For those cost reporting periods that would be used as the reference cost reporting period, which have been submitted to the Medicare contractor but not settled, Medicare contractors may perform desk or onsite audits related to section 5503. In addition, if the reference period cost report is for a period other than 12 months, we are proposing that for direct GME, the Medicare contractor would prorate the FTE resident caps and unweighted FTE resident count to equal 12-month counts.

c. Medicare GME Affiliation Agreements

As described above, some hospitals that have resident levels below their FTE resident caps may have entered into Medicare GME affiliation agreements (as permitted under §413.79(f) of our regulations) with other hospitals that would otherwise exceed their FTE resident caps. Thus, while some hospitals in the Medicare GME affiliated group were training a number of residents below their FTE resident caps prior to entering into a Medicare GME affiliation agreement, upon affiliating, their FTE resident caps

were temporarily reduced because some or all of their excess FTE slots were temporarily added to the FTE resident caps of other hospitals as part of the affiliation agreement. Under section 422 of Pub. L. 108–173, the statute directed us to apply the provisions to hospitals that were members of the same affiliated group as of July 1, 2003. In implementing section 422, we based the FTE resident cap reductions for hospitals that were participating in a Medicare GME affiliated group on the aggregate cap and count data from all hospitals participating in the same Medicare GME affiliated group(s). If a hospital was training a number of residents below its FTE resident cap for the reference cost reporting period but the hospital was part of a Medicare GME affiliated group for some or all of that reference cost reporting period, the Medicare contractor determined if the aggregate affiliated count for all hospitals in the affiliated group was greater than the aggregate affiliated cap. If the aggregate affiliated count was greater than the aggregate cap, then there was no reduction made to the FTE caps of any hospital in the affiliated group (even for a hospital that was part of the affiliated group, but was training below its cap). However, we note that, in contrast to section 422 of Pub. L. 108 – 173, section 5503 of the Affordable Care Act does not include language specific to affiliated groups. Rather, section 1886(h)(8)(H) of the Act, as added by section 5503 of the Affordable Care Act, defines the reference resident level and the otherwise applicable resident limit with respect to "a hospital." Similarly, section 1886(h)(8)(A) refers only to "a hospital's" reference resident level. Thus in contrast to section 422 of Pub. L. 108-173, section 5503 is not amenable to determinations based on the aggregate experience of a Medicare GME affiliated group. Therefore, we are proposing that Medicare contractors would make

determinations regarding FTE cap reductions under section 1886(h)(8)(A)(i) by considering the relationship of the individual hospital's otherwise applicable resident limit for the reference period (which is the FTE resident cap for a period as adjusted by any affiliation agreement(s)) to the individual hospital's reference resident level. That is, we are proposing that in a hospital's reference year, if that hospital is participating in a Medicare GME affiliated group and is training a number of residents below its FTE caps as adjusted pursuant to any affiliation agreements which can be found on Worksheet E, Part A, line 3.06 for IME, and Worksheet E-3 Part IV, line 3.03 for direct GME, the hospital's FTE resident caps would be subject to a reduction under section 1886(h)(8)(A)(i) even if the Medicare GME affiliated group as a whole may be training a number of residents above the group's aggregate FTE resident cap.

d. Treatment of Hospitals That Have Merged

We note that there may be instances where two hospitals merge on or after March 23, 2010, but were not merged in any or all of their three most recent cost reporting periods ending before March 23, 2010. For these hospitals, we are proposing that the Medicare contractors identify the hospitals' three most recent cost reporting periods ending before March 23, 2010, and treat the hospitals for purposes of section 1886(h)(8)(A)(i) as if they were merged during those periods in determining whether there should be a reduction to the merged facility's FTE resident cap(s). That is, we are proposing that for each of the 3 years, we would combine the FTE resident counts and caps of the formerly separate facilities in order to identify the reference period, and to calculate the reference resident level and the otherwise applicable resident limit for the

merged facility (for IME and direct GME respectively), even if the two facilities have different fiscal year ends. In addition, if any of the cost reporting periods are less than 12 months or greater than 13 months, the Medicare contractor would prorate the FTE resident counts and FTE caps for direct GME to equal a 12-month cost reporting period.

9. Application of Section 5503 to Hospitals That File Low Utilization Medicare Cost Reports

In general, section 5503 of the Affordable Care Act applies to Medicare-participating hospitals that train residents in approved residency training programs. However, some Medicare-participating hospitals may choose to submit low utilization cost reports. These low utilization cost reports may not contain the cost report worksheet that is used to calculate payments for direct GME, Worksheet E-3 Part IV. That is, these cost reports may not contain FTE resident count and cap information. For example, because Medicare-participating children's hospitals primarily serve a non-Medicare population and, therefore, receive minimal Medicare payments, some teaching children's hospitals submit low utilization cost reports. If a children's hospital files a low utilization cost report in a given cost reporting period, and does not file the Worksheet E-3 Part IV, that hospital is not considered by Medicare to be a teaching hospital for that cost reporting period. In addition, although children's hospitals may have an FTE resident "cap" that is applicable for purposes of the Children's Hospital Graduate Medical Education (CHGME) Payment Program, administered by HRSA, this cap is not necessarily used for Medicare payment purposes. Therefore, we are proposing that if a low utilization hospital does not have a cap for Medicare payment purposes, it

would not be subject to a negative cap reduction under section 5503. In addition, we are proposing that if a low utilization hospital does have a cap for Medicare payment purposes (for example, it had filed a regular cost report in 1996) but did not file Worksheet E-3 Part IV as part of its cost report in all three most recent cost reporting periods ending before March 23, 2010, it will be exempt from cap reduction. In addition, we are proposing that if a low utilization hospital has a cap for Medicare payment purposes and filed Worksheet E-3 Part IV in at least one of its three most recent cost reports ending before March 23, 2010, the Medicare contractor would determine, based on the data of the available cost reports with Worksheet E-3 Part IV, whether a cap reduction is necessary under section 1886(h)(8)(A)(i).

For those low utilization hospitals that have an FTE cap for Medicare payment purposes and have filed Worksheet E-3 Part IV in any of the three most recent cost reporting periods ending before March 23, 2010, we are proposing that determinations as to whether, and by how much, that low utilization hospital's cap may be reduced using the same methodology that we are proposing to use for other Medicare-participating teaching hospitals. In addition, for purposes of section 1886(h)(8)(B) of the Act, we are proposing that, a low utilization hospital would be eligible to apply for an increase in its FTE resident cap under section 1886(h)(8)(B) of the Act, subject to the same demonstrated likelihood and evaluation criteria proposed in this proposed rule for all other hospitals. However, as explained further below in this preamble, section 1886(h)(8)(B)(ii) of the Act, as added by section 5503(a)(4) of the Affordable Care Act, specifies certain requirements and thresholds that a hospital that receives additional slots

must meet in order to retain those slots. One requirement is that the hospital must ensure for a 5-year period that its number of FTE primary care residents is not less than the average number of FTE primary care residents during the 3 most recent cost reporting periods ending prior to March 23, 2010. Accordingly, we are proposing that an applying children's hospital must meet the same documentation requirements to establish this primary care average as other applying hospitals, which would mean that the children's hospital must have submitted a Worksheet E-3, Part IV with its Medicare cost report for those 3 most recent cost reporting periods ending prior to March 23, 2010. Furthermore, we are proposing that, in order to receive an increase in its FTE resident cap under section 1886(h)(8)(B) of the Act effective July 1, 2011, in addition to complying with the proposed application requirements as described in this preamble, the hospital would be required to file Worksheet E-3, Part IV, with its Medicare cost report for its cost reporting period that includes July 1, 2011 through and including its cost reporting period that includes June 30, 2016 (that is, the 5-year period). We are proposing that the low utilization hospital must meet this requirement because section 1886(h)(8)(B) is intended to allow a hospital to increase its FTE counts for purposes of Medicare GME payments. We do not believe it would be appropriate to grant an increase in a hospital's FTE resident cap under section 1886(h)(8)(B) of the Act if the hospital does not use the slots for Medicare purposes (but only, for example, for purposes of the CHGME Payment Program) as would be evidenced by not filing a Worksheet E-3, Part IV. Moreover, as explained further below, we are required under section 1886(h)(8)(B)(ii) and (iii) to

ensure certain levels of primary care or general surgery training, and the information in Worksheet E-3 Part IV, would be necessary for that purpose.

10. Treatment of Hospitals with Caps That Have Been Reduced or Increased under Section 422 of Pub. L. 108-173

For purposes of implementation of section 5503(a) of the Affordable Care Act, section 1886(h)(8)(H)(iii) of the Act states that the term "otherwise applicable resident limit," means, "with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraph (7)(A)." As noted earlier in this preamble, section 1886(h)(7)(A) of the Act, as added by section 422 of Pub. L. 108–173, provided for reductions to hospitals' caps if the hospitals were training a number of residents below their FTE resident caps during the relevant reference period, and for a "redistribution" that increased the FTE resident caps for certain hospitals. Although sections 1886(h)(4)(F)(i) and (H) refer to paragraph (7), which includes both cap reductions and increases made pursuant to section 422 of Pub. L. 108 – 173, we believe that specific mention of only paragraph (7)(A), which refers to cap reductions made under section 422, gives the Secretary the authority to only take into account the reductions made to hospitals' caps under section 1886(h)(7)(A), for purposes of implementing section 1886(h)(8)(A)(i) of the Act. That is, we believe specific mention of paragraph (7)(A) is meant to provide that in determining a hospital's otherwise applicable resident limit, the Secretary should take into account any reductions to its reference resident level made under section 1886(h)(7)(A) to determine whether a

cap reduction under section 1886(h)(8)(A)(i) is necessary. Furthermore, section 1886(h)(8)(H)(i) requires that for purposes of determining the reference resident level, the Secretary is required to consider the hospital's three most recent cost reporting periods ending prior to March 23, 2010 that have been settled (or, if not, submitted (subject to audit)), as determined by the Secretary. In addition, we note that increases made under section 1886(h)(7)(B) were effective for portions of cost reporting periods beginning on or after July 1, 2005, and that some hospitals may still be filling their residency training programs with FTE resident slots gained under section 1886(h)(7)(B), during what may be their reference cost reporting period for purposes of section 1886(h)(8)(A)(i). Therefore, we believe that it would be inappropriate to include increases made under section 1886(h)(7)(B) in determining the hospital's reference resident level for purposes of cap reductions under section 1886(h)(8)(A)(i). Hospitals that received increases to their caps under section 1886(h)(7)(B) may still be "building" their residency programs using the additional FTE resident slots they received under section 1886(h)(7)(B). Therefore, it would be premature to remove any of those FTE resident slots. Accordingly, we are proposing that, in determining whether a cap reduction is necessary under section 1886(h)(8)(A)(i) we would compare the hospital's FTE resident count for its reference period to its FTE resident cap, as adjusted under section 1886(h)(7)(A). We are proposing that we would <u>not</u> consider any increases to its resident cap a hospital may have received under section 1886(h)(7).

11. Criteria for Determining Hospitals That Will Receive Increases in Their FTE Resident Caps

Generally, under section 1886(h)(8)(A) of the Act, as added by section 5503(a)(4) of the Affordable Care Act, the Secretary is to reduce the FTE resident caps for hospitals that were training a number of residents below their otherwise applicable resident limit in the reference period by 65 percent of the "excess" resident slots. Under section 1886(h)(8)(B), the Secretary is to "redistribute" the estimated number of FTE reductions under section 1886(h)(8)(A) to increase the FTE resident caps for use by other hospitals. Under section 1886(h)(8)(B)(i) of the Act, the Secretary is authorized to increase the otherwise applicable FTE resident cap for each qualifying hospital that submits a timely application by a number that the Secretary may approve, for portions of cost reporting periods occurring on or after July 1, 2011. In implementing section 1886(h)(8)(B) of the Act, we note the difficulty in deciding which teaching hospitals are more "deserving" than others to receive the redistributed unused resident slots. Therefore, in addition to some considerations and priorities in redistribution that are specified in section 5503, we are proposing certain additional criteria that we believe will allow for an objective decision-making process.

Section 1886(h)(8)(B) of the Act, as added by section 5503 of the Affordable Care Act, establishes certain parameters in the statutory language for hospitals to meet to qualify to receive increases in their FTE resident caps. First, section 1886(h)(8)(B)(i) of the Act states that the aggregate number of increases in the otherwise applicable resident limits (caps) shall be equal to the aggregate reduction in the resident limits determined

under section 1886(h)(8)(A) of the Act as estimated by the Secretary(as discussed in section XVII.D of this proposed rule). Section 1886(h)(8)(F) of the Act states that in no case will any hospital receive an FTE cap increase of more than 75 FTE positions as a result of the redistribution. In addition, section 1886(h)(8)(C) of the Act specifies that, in determining which hospitals will receive the increases to their FTE resident caps, the Secretary is required to take into account the demonstrated likelihood that the hospital would be able to fill the position(s) within the first three cost reporting periods beginning on or after July l, 2011, and whether the hospital has an accredited rural training track program.

In setting up an application process for hospitals to apply for FTE resident cap increases from the redistribution pool (discussed in section XVII.D.8. of this proposed rule), we are proposing to consider the "demonstrated likelihood" criterion under section 1886(h)(8)(C)(i) as an eligibility criterion that a hospital must meet in order for CMS to further consider the hospital's application for an increase in its FTE resident cap. We are proposing that a hospital would meet the "demonstrated likelihood" criterion by demonstrating that it is either already training a number of FTE residents at or in excess of its current FTE caps (IME and direct GME FTE caps, respectively, <u>including any applicable section 422 cap add-on</u>), or that it does not have sufficient room under its current FTE caps to accommodate a planned new program or expansion of an existing program. We believe it is appropriate to consider a hospital's "demonstrated likelihood" as a requirement because we believe such hospitals will be best positioned to make immediate and efficient use of any FTE cap increase, and thereby, to use any resulting

increase in Medicare GME payments to train the physician workforce that will provide care to Medicare beneficiaries. Thus, we are proposing that, in order to be eligible for consideration for an increase under section 1886(h)(8)(B) of the Act, a hospital must first demonstrate the likelihood that it will able to fill the slots within the first three cost reporting periods beginning on or after July 1, 2011, by meeting at least one of the following three criteria and by providing documentation that it meets the criterion in its application for an increase to its FTE resident cap:

- Demonstrated Likelihood Criterion 1. The hospital does not have sufficient room under its current FTE cap for a new residency program that it intends to establish on or after July 1, 2011 (that is, a newly approved program that begins training residents at any point within the hospital's first three cost reporting periods beginning on or after July 1, 2011). Under this criterion, the hospital would select one of the following:

(1) Hospital will establish a newly approved residency program. (Under this selection, the hospital would be required to check at least one of the following, if applicable):

- Application for approval of the new residency program has been submitted to the ACGME, AOA, or the ABMS by December 1, 2010. (The hospital would be required to attach a copy.)
- The hospital has submitted an institutional review document or program information form concerning the new program in an application for

approval of the new program by December 1, 2010. (The hospital would be required to attach a copy.)

- The hospital has received written correspondence from the ACGME, AOA, or ABMS acknowledging receipt of the application for the new program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit). (The hospital would be required to attach a copy.)

(2) Hospital will likely fill the slots requested. (The hospital would be required to select at least one of the following, if applicable.)

- The hospital does not have sufficient room under its FTE cap, and the hospital's existing residency programs had a combined resident fill rate of at least 85 percent in each of program years 2007 through 2009. (The hospital would be required to attach documentation.)
- The hospital does not have sufficient room under its FTE cap, and the specialty program for which the hospital is applying has a resident fill rate either nationally, within the State, or within the CBSA in which the hospital is located, of at least 85 percent. (The hospital would be required to attach documentation.)

- Demonstrated Likelihood Criterion 2. The hospital does not have sufficient room under its FTE cap, and the hospital intends to use the additional FTEs to expand an existing residency training program within the hospital's first three cost reporting periods beginning on or after July 1, 2011.

(1) Hospital intends to expand an existing program. Under this selection, the hospital would be required to check at least one of the following, if applicable:

- The appropriate accrediting body (the ACGME, AOA, or ABMS) has approved the hospital's expansion of the number of FTE residents in the program. (The hospital would be required to attach documentation.)
- The American Osteopathic Association Residency Match Program has accepted or will be accepting the hospital's participation in the match for the existing program that will include additional resident slots in that residency training program. (The hospital would be required to attach documentation.)
- The hospital has submitted an institutional review document or program information form for the expansion of the existing residency training program by December 1, 2010. (The hospital would be required to attach documentation.)

(2) Hospital will likely fill the slots of the expanded existing residency program. Under this selection, the hospital would be required to check at least one of the following, if applicable:

- The hospital does not have sufficient room under its FTE cap, and the hospital has other previously established residency programs, with a resident fill rate of at least 85 percent in each of program years 2007 through 2009.) (The hospital would be required to attach documentation.)

- The hospital does not have sufficient room under its FTE cap, and the hospital is expanding an existing program in a particular specialty with a resident fill rate either nationally, within the State, or within the CBSA in which the hospital is located, of at least 85 percent. (The hospital would be required to attach documentation.)

- Demonstrated Likelihood Criterion 3. Hospital is applying for an increase in its FTE resident cap because the hospital is already training residents in an existing residency training program(s) in excess of its direct GME FTE cap or IME FTE cap, or both. The hospital would be required to attach copies of each of the following:

--Copies of the Medicare cost reports that have been most recently submitted to the Medicare contractor by July 1, 2010 documenting on Worksheet E, Part A, Worksheet E-3, Part VI, and Worksheet E-3, Part VI, the resident counts and FTE resident caps for both direct GME and IME for the relevant cost reporting periods.

--Copies of the 2010 residency match information concerning the number of residents at the hospital in its existing programs (that is, all programs, not only the ones for which the hospital may be requesting more slots).

--Copies of the most recent accreditation letters on all of the hospital's training programs in which the hospital trains and counts FTE residents for direct GME and IME.

We are proposing that each hospital applying for an increase under section 1886(h)(8)(B)(i) would be required to meet at least one of the above criteria in order to demonstrate the likelihood that it will be able to fill the additional slots associated with any increase in the hospital's FTE resident cap within the first three cost reporting

periods beginning on or after July 1, 2012. In other words, each hospital that wishes to apply for an increase in its FTE resident cap, as a preliminary matter, would be required to meet the "demonstrated likelihood" criterion in order for CMS to further consider the hospital's application for an increase in its FTE resident cap.

Although a hospital might be applying for additional slots for more than one specialty program, each application by a hospital must be program-specific. That is, the hospital would be required to complete a separate CMS evaluation form for each program and to demonstrate the likelihood of filling the slots in each program. However, in accordance with our general policy with respect to FTE resident caps, increases in hospital's FTE resident caps under section 1886(h)(8)(B)(i) for direct GME and IME, once granted to a hospital, would no longer be program-specific. Rather, the hospital's adjusted FTE resident caps would be applied to the hospital's FTE resident counts, including any residents the hospital trains. We note, however, that for FTE residents counted as a result of an increase in the FTE resident caps under section 422 of Pub. L. 108-173, payment is calculated separately for direct GME purposes using the national average PRA and, for IME purposes using a multiplier of 0.66 If a hospital receives an increase to its FTE resident cap(s) under section 5503, and also received a cap increase under section 422, we are proposing that the hospital would first assess whether it is training a number of residents in excess of its combined 1996 FTE and section 5503 caps and, only if its number of FTE residents still exceeds this combined cap would the separate 422 payment rates be applied to the excess FTEs for IME and direct GME respectively.

For purposes of the application for the increase to the FTE caps under section 1886(h)(8)(B)(i) of the Act, we are proposing to define “national fill rate” for each academic year, as we did when implementing section 422 of Pub. L. 108-173. That is, we defined “national fill rate” as the number of residents training in a program nationally as compared to the number of accredited slots in that program as of June 30 of that year. This information is available from the ACGME and the AOA. Furthermore, we are proposing to require that, for the purposes of an application for an increase to a hospital's FTE resident cap under section 1886(h)(8)(B) of the Act, a hospital must use the “fill rate” for the most recent academic year for which data are available.

We understand that hospitals may train fewer residents than the number of available accredited slots in their approved programs due to reasons other than an inability to fill those slots. Furthermore, because we understand that a national fill rate is not necessarily the only indicator of the ability of hospitals to fill residency positions in its CBSA or State, and there may be characteristics particular to a region, such as population density, variety of practice settings, or access to technology or procedures that may allow a specified area to have a fill rate in a specific program that exceeds the program’s national fill rate, we are proposing several options for a hospital to satisfy the “fill rate’" criterion. In part, as when implementing section 422 of Pub. L. 108-173, we specified that the fill rate “threshold” is 85 percent. We believe that this rate will reasonably identify those programs that are likely to fill FTE resident positions in newly approved or expanded programs (while providing some latitude to account for other factors that affect the national fill rate), and to fully utilize an increase in FTE resident

cap slots that may be available under section 1886(h)(8)(B) of the Act as added by section 5503. We are proposing that a hospital may demonstrate the likelihood of filling FTE resident positions associated with a possible increase in its FTE resident cap under section 5503 by documenting that any of the following applies to the new program or to an expansion of an existing program:

- The specialty program has a resident fill rate nationally, across all hospitals, of at least 85 percent.
- The specialty program has a resident fill rate within the State in which the hospital is located of at least 85 percent.
- If the hospital is located within an urban CBSA, the specialty program has a resident fill rate within the CBSA of at least 85 percent.

For the purposes of demonstrating the likelihood of filling FTE resident positions under section 1886(h)(8)(C)(i) of the Act, as added by section 5503, we are proposing that "national fill rate" means, for the most recent academic year for which data is available, the number of residents training in a program nationally (combined allopathic and osteopathic residents) compared to the number of accredited slots in that program nationally as of June 30 of that year. The proposed Demonstrated Likelihood Criterion 1 and Demonstrated Likelihood Criterion 2 also allow a hospital to demonstrate the likelihood of filling the requested slots by demonstrating that the hospital's existing residency programs had a "resident fill rate" of at least 85 percent in each program year from 2007 through 2009. For the purpose of fulfilling these demonstrated likelihood criteria, we are proposing to define "resident fill rate" to mean, for the most recent

academic year for which data is available, the number of residents training in each program in total at a particular hospital as compared to the number of accredited slots in each program in total at that hospital as of June 30 of that year.

We also understand that, for certain programs, because of the length of the accreditation process and a relatively long match period, a hospital may be unable to accept its first class of PGY-1 residents until July 1, 2012. We are proposing that the hospital may still apply to receive a full complement of residents for the 3 years beginning July 1, 2012, assuming the applicant hospital can demonstrate the likelihood that it will fill the slots relating to a possible increase in its FTE resident caps under section 1886(h)(8)(B)(i). However, if the applicant hospital does not demonstrate the likelihood that it will fill <u>any</u> FTE slots for programs described by the hospital on the CMS evaluation form(s) at <u>any</u> point within the hospital's first three cost reporting periods beginning on or after July 1, 2011, the hospital would not be eligible for further consideration by CMS of an increase to the hospital's FTE caps under section 1886(h)(8)(B)(i). Accordingly, our proposed Demonstrated Likelihood Criterion 1 would reflect that the hospital does not have sufficient room under its FTE cap to train residents in a newly approved residency program that it demonstrates it will establish within the hospital's first three cost reporting periods beginning on or after July 1, 2011 (that is, a newly approved program that begins training residents *at any point within the hospital's first three cost reporting periods beginning on or after July 1, 2011*)" (emphasis added).

Under Demonstrated Likelihood Criterion 3, we are proposing to allow a hospital that is already training a number of FTE residents in an existing residency training program(s) in excess of its direct GME FTE cap or IME FTE cap, or both, to meet the demonstrated likelihood requirement. In order to document that it meets this criterion, a hospital would be required to submit copies of the 2010 "residency match" information concerning the number of residents the hospital has in an existing program. We believe the most recent match information could indicate that the hospital is expected to take in more residents than the number of cap slots it has available. For purposes of the application of this demonstrated likelihood criterion, we are defining "residency match" as a national process administered by the National Residency Matching Program (NRMP), including the NRMP's Specialties Matching Service, the San Francisco Matching Program, the American Osteopathic Association Residency Match Program, or the Urology Matching Program, by which applicants to approved medical residency programs are paired with programs on the basis of preferences expressed by both the applicants and the program directors.

We also note that under Demonstrated Likelihood Criteria 2 and 3, the hospital would be applying for an increase in its FTE cap because it is expanding an *existing* residency program, or it is already training residents in an *existing* residency training program(s) in excess of its FTE caps, respectively. By existing program, we are proposing that, as of July 1, 2010, the hospital is either already training residents in this program or programs, or the program exists at another hospital prior to July 1, 2011, but the residents begin to rotate at the applying hospital on or after July 1, 2011. We are

providing several proposed methods for hospitals to be able to demonstrate to CMS under the proposed Demonstrated Likelihood Criterion 1 that they can fill the slots by showing to CMS that they are establishing a new residency program on or after July 1, 2011. We believe hospitals that establish new residency programs before July 1, 2011, could possibly also meet Demonstrated Likelihood Criterion 2, relating to a hospital that is expanding an existing residency program on or after July 1, 2011. From the perspective of applying for the cap increase under section 1886(h)(8)(B)(i), the new program that starts training residents in 2010 is an "existing residency program" because it began before July 1, 2011, and it is "expanding" if that program is increasing in the number of FTE residents in the first three cost reporting periods beginning on or after July 1, 2011.

We note that the listing of programs participating in the AOA Match Program will be available on the National Matching Services Web site as of November 1, 2010. Therefore, we are proposing that programs utilizing the AOA Match Program may, in addition to the two options listed above, demonstrate the intent to expand an existing program by documenting that the AOA has accepted the hospital's participation in the match program by the December 1, 2010 application deadline. Therefore, we are proposing that this method of demonstrating the hospital's intent to expand an existing program will be applicable for programs participating in the AOA Match Program.

12. Application Process for the Increases in Hospitals' FTE Resident Caps

In order for hospitals to be considered for increases to their FTE resident caps under section 1886(h)(8)(B)(i) of the Act, as added by section 5503(a)(4) of the Affordable Care Act, we are proposing to require that each qualifying hospital submit a

timely application by December 1, 2010. As part of the requirements that a hospital must fulfill in order to complete an application for an increase to its FTE resident caps, we are proposing to require that the applicant hospital must include the total number of requested FTE resident slots (for all residency programs) for direct GME or IME, or both (not to exceed 75 FTEs for each, as specified under section 1886(h)(8)(F) of the Act). Thus, we would require that the hospital's total requests for increases in the IME and the direct GME caps (that is, the total number of requested FTE resident slots increases (for all residency programs at the hospitals)) would be required to be indicated on the same application for an increase under section 1886(h)(8)(B)(i). We are proposing that each hospital must submit the following information on its application for an increase in its FTE resident cap:

- The name and Medicare provider number of the hospital, and the name of the Medicare contractor to which the hospital submits its cost report.
- The total number of requested FTE resident slots (for all residency programs at the hospital) for direct GME or IME, or both (not to exceed 75 FTEs each).
- A completed copy of the CMS evaluation form (as described below) for each residency program for which the applicant hospital intends to use the requested increase in the number of FTE residents and source documentation to support the assertions made by the hospital on the evaluation form. (For example, if the hospital checks off on the evaluation form that the hospital is starting a new geriatrics program, the hospital would include documentation to support that assertion.)

- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report. (The hospital would be required to include copies of Worksheets E, Part A, E-3, Part IV, and if a hospital received an increase to its FTE cap(s) under section 422 of Pub. L. 108-173, a copy of E-3, Part VI.)

- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following information in the hospital's application for an increase in its FTE resident cap:

"I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents."

We are proposing that any hospital that wishes to apply for an increase in its FTE resident cap(s) under section 1886(h)(8)(B)(i) must submit a copy of its completed application (as described above) to the CMS Central Office and to the CMS Regional

Office for the region in which the applicant hospital is located, and that the application must be received by CMS on or before December 1, 2010. (The mailing addresses for the CMS offices are indicated at the end of this section of the preamble.) We note that some hospitals' FTE counts will be subject to audit for purposes of possible cap reductions under section 1886(h)(8)(A)(i), and those audits may not be completed by December 1, 2010. Because the results of such an audit may be a factor in a hospital's decision whether to request an increase in its FTE resident cap under section 1886(h)(8)(B)(i) of the Act, we are proposing to allow a later date for those hospitals to apply for increases in their FTE resident caps. Therefore, if a hospital's resident level is audited for purposes of section 1886(h)(8)(A) of the Act, whether or not the hospital's FTE resident caps are reduced under section 1886(h)(8)(A) of the Act, if that hospital wishes to apply for an increase in its FTE resident cap(s) available under section 1886(h)(8)(B)(i) of the Act, we are proposing that the hospital must submit a completed application to CMS and that the application must be received on or before March 1, 2011.

We note that, although a hospital might be applying for an increase to its FTE caps either to start a new program or expand a particular program, the FTE caps are not program-specific; but rather, they are hospital-specific. A hospital, and not a particular residency training program, would be applying for an increase to its FTE caps. We are proposing that all completed applications that are timely received according to the above deadlines would be evaluated by CMS according to the criteria described under section XVII.D. of this proposed rule for determining the priority distribution of FTE resident

slots. Hospitals that satisfy at least one of the "demonstrated likelihood" criteria would be further evaluated by the evaluation criteria described below.

13. CMS Evaluation of Applications for Increases in FTE Resident Caps

We are proposing to require hospitals to submit, with their applications for increases in their FTE resident caps, a completed copy of the CMS Evaluation Form. The CMS Evaluation Form will ask the hospital to check off which of the "demonstrated likelihood" criteria (described above in section XVII.D.11. of this proposed rule) the hospital meets. We also are proposing to require that the hospital provide the documentation that supports the "demonstrated likelihood" criteria it has checked off on the Evaluation Form.

Assuming that the applicant hospital meets the "demonstrated likelihood" requirement, we are proposing that the applicant hospital would indicate on the CMS Evaluation Form the category(ies) for which it believes it will qualify. We would use this indication to prioritize the applications. This prioritization is derived from section 1886(h)(8)(C) and (D) of the Act, as added by section 5503 of the Affordable Care Act. That section established considerations in redistribution and a priority order that must be applied in determining the hospitals that will receive increases in their FTE caps. As discussed above, the first consideration in redistribution is that the applicant hospital must demonstrate the likelihood of filling the slots requested within the first three cost reporting periods beginning on or after July 1, 2011. Another consideration is "whether the hospital has an accredited rural training track" (as described in section 1886(h)(4)(H)(iv) of the Act). Accordingly, we are proposing that, in distinguishing

between hospitals within a priority category, and determining which hospitals will receive FTE cap increases, we would give preference to a hospital that has an accredited rural training track over a hospital that does not have such a program. Under section 1886(h)(4)(H)(iv) of the Act, as implemented in the regulations at §413.79(k), an urban hospital that operates a rural training track (often known as separately accredited 1-2 tracks in family medicine) wherein residents rotate at the urban hospital for less than one-half of the duration of the program, and to a rural area for the remainder of the program, the urban hospital may include in its FTE count the FTE resident time spent training in the rural track, even if that time would be in excess of the hospital's FTE cap. We note that if an urban hospital is interested in starting a new rural training track, it need not apply for additional slots under section 1886(h)(8)(B)(i). Rather, under the existing regulations at §413.79(k), the urban hospital may receive an increase to its FTE cap to reflect FTE residents training in the rural track. (For more details on rural training tracks, and the direct GME and IME payment rules associated with them, we refer readers to 66 FR 39902, August 1, 2001, and 68 FR 45454, August 1, 2003). However, because section 1886(h)(8)(C) of the Act states that the Secretary shall take into account "whether the hospital <u>has</u> an accredited rural training track" (emphasis added), we are proposing that an applying urban hospital that either <u>has</u> a separately accredited rural training track, or can document that it <u>will have</u> a separately accredited rural training track as of July 1, 2011, may receive preference over a hospital that, all other things being equal, does not and will not have a rural training track by that date. We note that section 1886(h)(8)(C) of the Act does not specify that a hospital must be applying for additional

slots in order to expand its existing rural training track in order to qualify to receive additional slots. Rather, section 1886(h)(8)(C) of the Act merely states that "the Secretary shall take into account . . . whether the hospital has an accredited rural training track (as described in paragraph (4)(H)(iv))" (emphasis added). That is, the fact that an urban hospital already has (or, under this proposed rule, would have as of July 1, 2011) a separately accredited rural training track is sufficient to give preference in redistribution to such a hospital.

Section 1886(h)(8)(D) of the Act instructs the Secretary to "distribute the increase to hospitals based on the following factors":

- Whether the hospital is located in a State with a resident-to-population ratio in the lowest quartile (as determined by the Secretary) (section 1886(h)(8)(D)(i) of the Act).

In order to determine which States are in the lowest quartile for resident-to-population ratios, we are proposing to use three sources of data, and the latest data available for each of those three sources. First, we are proposing to determine the number of allopathic residents in each state by using data from the ACGME's Data Resource Book for the Academic Year 2008-2009. As of publication of this proposed rule, this is the most recent data available from the ACGME. In this book, which is available free of charge on the ACGME's Web site, is a table titled "Number of Residents in Core and Subspecialty Programs, by State" (www.acgme.org/acWebsite/dataBook/2008-2009_ACGME_Data_Resource_Book.pdf). This table lists each State (including Puerto Rico), and includes a column called "Number of Residents." We are proposing to use the data from this column called "Number of Residents" as part of the numerator to

determine the resident-to-population ratio in each state. However, because these data only include residents enrolled in ACGME-accredited programs, we also are proposing to add to these numbers the number of residents enrolled in AOA-accredited programs. We are proposing to access data on the number of osteopathic residents in each State from the AOA, which was provided to CMS upon special request. These data are what is generally published in the AOA's Journal of the American Osteopathic Association (JAOA). As of the issuance of this proposed rule, the most recent data published in JAOA was that for the 2007-2008 academic year. However, because we have data from the ACGME for the 2008-2009 academic year, we requested and received data from the AOA for the 2008-2009 academic year as well. Although these data will not be published in the JAOA for some months, we have received permission from the AOA to publish it in this proposed rule (as indicated at the end of the GME discussion). These data are also presented in the form of a table listing each State (there are no osteopathic programs in Puerto Rico), and a column for the total number of residents in each State. Therefore, we are proposing that the numerator for the ratio for each State would be the sum of the residents from the 2008-2009 ACGME's table for that State, and the residents from the 2008-2009 AOA table for that State.

We understand that, although graduates of allopathic medical schools are precluded from training in AOA-accredited programs, there is no similar prohibition on osteopathic residents training in allopathic programs. Because there are osteopathic residents who enroll and participate in allopathic ACGME-accredited programs, we want to ensure that there is no double counting of residents in the numerator. We have learned

from the ACGME that their data in the ACGME Data Resource Book include osteopaths, but only those training in ACGME-accredited programs. The AOA data do not include osteopathic residents who are training in ACGME-accredited programs; AOA data only include osteopathic residents enrolled and training in AOA-accredited programs. Therefore, we do not believe there is a concern about double counting with respect to osteopathic residents training in allopathic programs. However, we also are aware that there are some programs that are dually accredited by the ACMGE, and the AOA, and residents completing these programs are able to sit for both the ABMS and the AOA board examination in that specialty. We understand that the ACGME will include a resident in its resident count as long as that resident is training in an ACGME-accredited program, even if that program is dually accredited. The AOA has the same practice of including in its total count of residents those who are in AOA-accredited programs, even if it is a dual eligible program. Therefore, there is some degree of unavoidable double counting of residents in the total count. However, we understand that the number of residents in dually-accredited programs is less than 500, and because 500 is only 0.44 percent of the combined ACGME and AOA 2008-2009 resident count of 114, 416, we believe the effect of counting these residents by both the ACGME and AOA is negligible and would not harm the integrity of the data.

We are proposing to define “resident” in “resident-to-population” ratio as actual individual residents, as opposed to the FTE resident figures that are used for Medicare payment purposes. We believe it is appropriate to define “residents” as actual individual residents in this instance because the intent behind this criterion is to identify those States

that have low numbers of physicians-in-training in relation to the general population for which those physicians-in-training are providing health care services. An "FTE" measure, which is the measure used for most Medicare payment purposes, does not accurately reflect the number of individual physicians-in-training providing services in a State.

With regard to State population data to be used in the denominator of each State's resident-to-population ratio, we again are proposing to use the latest available data on State populations. We are proposing to use data from the Census Bureau that is from the 2000 Census, but that have been updated with the most recent data available as of July 1, 2009. We accessed these data from the following Web site: http://www.census.gov/popest/datasets.html. On this Web page, the following data can be found: State population datasets -- Population, population change and estimated components of population change: April 1, 2000 to July 1, 2009 (NST-EST2009-alldata). We are proposing to use the CSV file at this link. Specifically, we are proposing to use the data for State population from the column called POPESTIMATE2009 (column Q of the CSV spreadsheet). Therefore, we are proposing to determine each State's resident-to-population ratio, and specifically those States that fall within the lowest quartile by using the sum of the 2008-2009 ACGME and AOA resident data for each State, as described above, in the numerator for each State, and by using the population data updated as of July 1, 2009 in the denominator for each State from the column called POPESTIMATE2009 in column Q of the CSV spreadsheet. The following table lists

each State, and is sorted by resident-to-population ratio from lowest to highest. The first 13 shaded states are the states in the lowest quartile.

State Name	Census data as of July 1, 2009	ACGME resident data 2008-2009	AOA resident data 2008-2009	Total resident data	Resident to population ratio
Montana	974,989	20	0	20	0.0021%
Idaho	1,545,801	50	0	50	0.0032%
Alaska	698,473	35	3	38	0.0054%
Wyoming	544,270	40	4	44	0.0081%
Nevada	2,643,085	242	48	290	0.0110%
South Dakota	812,383	97	0	97	0.0119%
North Dakota	646,844	107	0	107	0.0165%
Mississippi	2,951,996	495	0	495	0.0168%
Florida	18,537,969	3,331	293	3,624	0.0195%
Puerto Rico Commonwealth	3,967,288	801	0	801	0.0202%
Indiana	6,423,113	1,278	20	1,298	0.0202%
Arizona	6,595,778	1,296	45	1,341	0.0203%
Georgia	9,829,211	2,044	8	2,052	0.0209%
Oregon	3,825,657	805	0	805	0.0210%
Colorado	5,024,748	1,135	0	1,135	0.0226%
Arkansas	2,889,450	703	3	706	0.0244%
South Carolina	4,561,242	1,115	8	1,123	0.0246%
Utah	2,784,572	687	0	687	0.0247%
Washington	6,664,195	1,652	0	1,652	0.0248%
Kansas	2,818,747	694	6	700	0.0248%
Oklahoma	3,687,050	735	189	924	0.0251%
Alabama	4,708,708	1,201	0	1,201	0.0255%
California	36,961,664	9,658	176	9,834	0.0266%
Maine	1,318,301	295	56	351	0.0266%
Kentucky	4,314,113	1,119	31	1,150	0.0267%
New Mexico	2,009,671	534	5	539	0.0268%
New Hampshire	1,324,575	368	4	372	0.0281%
Iowa	3,007,856	816	29	845	0.0281%
Texas	24,782,302	6,993	101	7,094	0.0286%
Virginia	7,882,590	2,229	46	2,275	0.0289%
Wisconsin	5,654,774	1,660	21	1,681	0.0297%
North Carolina	9,380,884	2,817	14	2,831	0.0302%
Hawaii	1,295,178	415	0	415	0.0320%
Tennessee	6,296,254	2,089	2	2,091	0.0332%
New Jersey	8,707,739	2,731	319	3,050	0.0350%
Nebraska	1,796,619	641	0	641	0.0357%

State Name	Census data as of July 1, 2009	ACGME resident data 2008-2009	AOA resident data 2008-2009	Total resident data	Resident to population ratio
Delaware	885,122	306	18	324	0.0366%
Louisiana	4,492,076	1,666	0	1,666	0.0371%
West Virginia	1,819,777	620	96	716	0.0393%
Minnesota	5,266,214	2,144	0	2,144	0.0407%
Vermont	621,760	259	0	259	0.0417%
Missouri	5,987,580	2,514	114	2,628	0.0439%
Maryland	5,699,478	2,632	0	2,632	0.0462%
Illinois	12,910,409	5,728	261	5,989	0.0464%
Ohio	11,542,645	5,293	565	5,858	0.0508%
Connecticut	3,518,288	2,010	13	2,023	0.0575%
Michigan	9,969,727	4,574	1,196	5,770	0.0579%
Pennsylvania	12,604,767	7,236	737	7,973	0.0633%
Rhode Island	1,053,209	725	0	725	0.0688%
Massachusetts	6,593,587	5,195	14	5,209	0.0790%
New York	19,541,453	15,821	489	16,310	0.0835%
District of Columbia	599,657	1,831	0	1,831	0.3053%

Based on the foregoing proposed data, the following States fall within the lowest quartile for resident-to-population ratios: Montana, Idaho, Alaska, Wyoming, Nevada, South Dakota, North Dakota, Mississippi, Florida, Puerto Rico, Indiana, Arizona, and Georgia. Accordingly, we are proposing that, consistent with section 1886(h)(8)(D)(i) of the Act, a hospital located in any one of these States that applies for an increase to its FTE cap under section 1886(h)(8)(B) of the Act would receive preference over a hospital that is applying for an increase to its cap that is not located in one of these States.

- Whether the hospital is located in a State, a territory of the United States, or the District of Columbia that is among the top 10 States, territories, or Districts in terms of (1) the total population of the State, territory, or District living in an area designated (under such section 332(a)(1)(A)) as a health professional shortage area (as of the date of

enactment of this paragraph); to (2) the total population of the State, territory, or District (as determined by the Secretary based on the most recent available population data published by the Bureau of the Census).

In order to determine which applying hospitals fall within this priority category, we need to determine the total population living in a HPSA in each State, territory, or District computed "as of the date of enactment," and we need to determine the total population of each State, territory, or District "(as determined by the Secretary based on the most recent available population data published by the Bureau of the Census)." "Territory" is referring to Puerto Rico, which currently has teaching hospitals, and "District of Columbia" refers to Washington D.C. For ease of reference, and consistent with the definition of "State" at section 210 of the Act, we are proposing to refer to "State, territory, or District" simply as "State." We have received data on the population of each HPSA from the Health Resources and Services Administration's (HRSA) Geospatial Warehouse. HRSA's Shortage Designation Branch develops shortage designation criteria and uses them to decide whether or not a geographic area, or population group, is a HPSA. HRSA updates HPSA statistics on its Web site on a daily basis, and we have requested and received the data reflective of the "date of enactment"; that is, March 23, 2010. Because HRSA updates the data on its Web site daily, the data as of March 23, 2010 are no longer available on its Web site. (General information on HPSAs and current data can be found on HRSA's Web site at: http://bhpr.hrsa.gov/shortage/).

HRSA designates three different kinds of HPSAs: Primary Care HPSAs, Dental HPSAs, and Mental Health HPSAs. While many areas may only be designated as one of these kinds of HPSAs, some areas may be designated as two or three of these kinds of areas. Thus, if we were to add the population in each State that is in a Primary Care HPSA, a Dental HPSA, and a Mental Health HPSA, we would be duplicating the HPSA populations in each State. Therefore, we are proposing to use only the population in each State that is in a Primary Care HPSA. We believe that it is appropriate to choose to recognize only the Primary Care HPSAs in each State for the purpose of implementing section 5503 because section 5503 is intended to encourage an increase in the number of primary care residents that are currently being trained in hospitals, as is evidenced by the "Requirements" in section 1886(h)(8)(B)(ii) of the Act, as added by section 5503(a)(4), which requires hospitals that receive additional slots under this section to maintain a certain average number of primary care resident positions, and that not less than 75 percent of the redistributed positions must be awarded for slots used in a primary care or a general surgery residency.

With respect to data on each State's total population "as determined by the Secretary based on the most recent available population data published by the Bureau of the Census," we are proposing to use the same data that we are using under the first priority category with regard to determining resident-to-population ratios, as explained above. These data, which are the most recent available, were last updated on July 1, 2009. As explained above, we accessed these data from the following Web site: http://www.census.gov/popest/datasets.html. On this Web page, the following data can

be found: State population datasets -- population change and estimated components of population change: April 1, 2000 to July 1, 2009 (NST-EST2009-alldata). We are proposing to use the CSV file at this link. Specifically, we are proposing to use the data for State population from the column called POPESTIMATE2009 (column Q of the CSV spreadsheet).

The following table lists each State, its Primary Care HPSA population-to-State population ratio from highest to lowest, and whether that State falls within the top 10 States for such Primary Care HPSA population-to-State population ratios:

State Name	Census data as of July 1, 2009	Primary Care HPSA	Primary Care HPSA to Population Ratio
Louisiana	4,492,076	3,119,598	69.4467%
Mississippi	2,951,996	1,781,774	60.3583%
Puerto Rico Commonwealth	3,967,288	2,282,408	57.5307%
New Mexico	2,009,671	1,036,774	51.5892%
South Dakota	812,383	351,926	43.3202%
District of Columbia	599,657	257,377	42.9207%
Montana	974,989	384,030	39.3881%
North Dakota	646,844	239,550	37.0337%
Wyoming	544,270	199,656	36.6833%
Alabama	4,708,708	1,725,293	36.6405%
Arizona	6,595,778	1,981,387	30.0402%
Illinois	12,910,409	3,858,062	29.8833%
Missouri	5,987,580	1,780,841	29.7422%
Idaho	1,545,801	453,347	29.3276%
Kentucky	4,314,113	1,155,928	26.7941%
South Carolina	4,561,242	1,159,709	25.4253%
Texas	24,782,302	6,040,714	24.3751%
Delaware	885,122	215,060	24.2972%
New York	19,541,453	4,691,714	24.0090%
Oklahoma	3,687,050	866,358	23.4973%
Georgia	9,829,211	2,276,546	23.1610%
Florida	18,537,969	4,287,169	23.1264%
Tennessee	6,296,254	1,455,365	23.1148%
Alaska	698,473	153,999	22.0480%
Kansas	2,818,747	570,639	20.2444%

State Name	Census data as of July 1, 2009	Primary Care HPSA	Primary Care HPSA to Population Ratio
Colorado	5,024,748	970,145	19.3073%
Michigan	9,969,727	1,916,653	19.2247%
Nevada	2,643,085	504,174	19.0752%
North Carolina	9,380,884	1,673,482	17.8393%
Iowa	3,007,856	536,519	17.8373%
Wisconsin	5,654,774	998,920	17.6651%
West Virginia	1,819,777	318,133	17.4820%
Arkansas	2,889,450	501,208	17.3461%
Utah	2,784,572	477,193	17.1370%
Washington	6,664,195	1,140,882	17.1196%
California	36,961,664	6,014,851	16.2732%
Virginia	7,882,590	1,222,771	15.5123%
Oregon	3,825,657	579,368	15.1443%
Rhode Island	1,053,209	156,064	14.8180%
Connecticut	3,518,288	477,837	13.5815%
Massachusetts	6,593,587	893,375	13.5492%
Indiana	6,423,113	816,234	12.7078%
Maine	1,318,301	156,116	11.8422%
Ohio	11,542,645	1,326,610	11.4931%
Pennsylvania	12,604,767	1,431,314	11.3553%
Minnesota	5,266,214	493,764	9.3761%
Maryland	5,699,478	523,260	9.1808%
Nebraska	1,796,619	146,196	8.1373%
Hawaii	1,295,178	93,107	7.1887%
Vermont	621,760	40,313	6.4837%
New Hampshire	1,324,575	84,038	6.3445%
New Jersey	8,707,739	376,405	4.3226%

- Whether the hospital is located in a rural area (as defined in section 1886(d)(2)(D)(ii) of the Act). Section 1886(d)(2)(D)(ii) of the Act defines a rural area as any area outside a MSA. Under the existing regulations at §412.62(f)(ii), an "urban area" means (1) a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA); or (2) the following New England counties: Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island. Under existing §412.62(f)(iii), a "rural

area" means any area outside an urban area. Thus, for purposes of the amendments made by section 5503, we are proposing that any hospital located in an area that is not in a MSA is a rural hospital, regardless of any reclassification under §412.102 or §412.103. We also point out that, since FY 2005, we no longer use the term MSA, but instead use CBSA, or Core-Based Statistical Area. There are urban CBSAs, and rural CBSAs are areas outside of an urban CBSA. We note that this definition of "rural" is consistent with our policy concerning designation of wage index areas.

We also are proposing that, in determining which applicant hospitals receive priority within the priority category of hospitals located in a State in the lowest quartile for resident-to-population ratios that hospitals in a State that is ranked lower in the quartile (with number one being the lowest) would receive preference over hospitals in states that are still within the quartile, but ranked higher. For example, all other things being equal, a hospital located in Montana would receive preference over a hospital located in Idaho, while this hospital would receive preference over a hospital located in Alaska, and so on. Similarly, we are proposing that, in determining which applicant hospitals receive priority within the priority category of hospitals located in a State that is among the top 10 of these areas in terms of the ratio of Primary Care HPSA population to total population, hospitals in an area that is ranked higher in the top 10 (with number 1 being highest and number 10 being lowest) would receive preference over hospitals in an area that are still within the top 10, but ranked lower. For example, all other things being equal, a hospital located in Louisiana would receive preference over a hospital located in

Mississippi, while a hospital in Mississippi would receive preference over a hospital located in Puerto Rico, and so on.

As we described above, we are proposing that an applicant hospital indicate on the CMS Evaluation Form the category(ies) for which it believes it will qualify, and we will use this indication to prioritize the applications. Each of the categories (described below) is derived from the priorities established by section 1886(h)(8)(D) of the Act, as added by section 5503 of the Affordable Care Act. We are proposing to use the following categories to determine the order in which hospitals would be eligible to receive increases in their FTE resident caps:

- First Level Priority Category: The hospital is in a State whose resident-to-population ratio is within the lowest quartile, AND the hospital is in a State whose Primary Care HPSA to population ratio is in the top 10 States, AND the hospital is located in a rural area.

- Second Level Priority Category: The hospital is in a State whose resident-to-population ratio is within the lowest quartile, AND is either in a State whose Primary Care HPSA to population ratio is in the top 10 States, or it is located in a rural area, or is an urban hospital and has or will have as of July 1, 2010, a rural training track.

- Third Level Priority Category: The hospital is in a State whose resident-to-population ratio is within the lowest quartile.

- Fourth Level Priority Category: The hospital is in a State whose Primary Care HPSA to population ratio is in the top 10 States, AND either the hospital is located in a

rural area or the hospital is an urban hospital and has, or will have as of July 1, 2010, a rural training track.

- Fifth Level Priority Category: The hospital is in a State whose Primary Care HPSA to population ratio is in the top 10 States, or the hospital is located in a rural area.

We believe it is appropriate to establish priority level categories based on the fact that some hospitals that apply for the additional resident slots may fit into more than one of the three statutory priority categories listed in section 1886(h)(8)(D) of the Act. Therefore, we are proposing to give consideration first to those hospitals that meet more than one of the statutory priority categories over those hospitals that meet only one of the statutory priorities. We are further proposing that a hospital that is in a State whose resident-to-population ratio is within the lowest quartile would receive priority over a hospital that is not located in one of these States. We believe this is consistent with the direction established at section 1886(h)(8)(E)(i) of the Act which specifies that the Secretary shall reserve 70 percent of all positions available for distribution for hospitals in a State whose resident-to-population ratio is within the lowest quartile. Only 30 percent of the positions are to be distributed to hospitals in States whose Primary Care HPSA to population ratio is in the top 10 States, and hospitals located in rural areas. In addition, as discussed above, the first consideration in redistribution under section 1886(h)(8)(C) of the Act is that the applicant hospital must demonstrate the likelihood of filling the slots requested within the first three cost reporting periods beginning on or after July 1, 2011. The second consideration is "whether the hospital has an accredited rural training track" (as described in section 1886(h)(4)(H)(iv) of the Act). Accordingly, we are proposing that, in distinguishing between hospitals within priority categories, and

in determining which hospitals qualify to receive additional slots, we would give preference to a hospital that has an accredited rural training track as compared to a hospital that does not have such a program.

Because section 1886(h)(8)(E) of the Act specifies that 70 percent of the slots are to be reserved for hospitals that are in a State whose resident-to-population ratio is within the lowest quartile, and 30 percent of the positions are to be reserved for hospitals in States whose Primary Care HPSA to population ratio is in the top 10 States, and hospitals located in rural areas, we are proposing that no slots would be given to hospitals that do not fit within either of these categories.

14. CMS Evaluation of Application for Increases in FTE Resident Caps—Evaluation Criteria

We anticipate that there will be a limited number of slots available for distribution from the redistribution pool, while there will be a great demand for those limited slots. Therefore, as we did when implementing section 422 of Pub. L. 108-173, we are proposing to use additional criteria (some of which are the same as those used to implement section 422) for evaluating the applications for increases in hospitals' FTE resident caps within each of the seven level priority categories described above under section 5503. In addition, in implementing section 5503, we are proposing to assign a certain number of points to each evaluation criterion, such that some will be worth more points than others. We note that the criteria are not mutually exclusive. Hospitals may qualify for a number of different criteria and their "score" is the total point value for all criteria met by the hospital for each program. Because we anticipate that the

redistribution pool under section 5503 will be smaller than that under section 422, we believe a more rigorous and competitive ranking system is appropriate under section 5503. Thus, we are assigning a different amount of points to each Evaluation Criterion, rather than just assigning one point to each.

Evaluation Criterion One. *The hospital that is requesting the increase in its FTE resident cap(s) has a Medicare inpatient utilization over 60 percent, as reflected in at least two of the hospital's last three most recent audited cost reporting periods for which there is a settled cost report.* (5 Points) We have selected 60 percent utilization because we believe that level would identify hospitals where Medicare beneficiaries will benefit the most from the presence of a residency program, and it is consistent with the utilization percentage required for Medicare-dependent, small rural hospitals (MDHs) as specified in §412.108. In addition, it identifies a type of hospital that warrants atypical treatment by the Medicare program because it is so reliant on Medicare funding.

Evaluation Criterion Two. *The hospital will use the additional slots to establish a new geriatrics residency program, or to add residents to an existing geriatrics program.* (5 Points) Section 5503 places a particular emphasis on increasing the number of residency positions in primary care specialties, as evidenced by the requirement at section 1886(h)(8)(B)(ii) of the Act that a hospital that receives slots must maintain at least the same number of primary care residents as it had during the three most recent cost reporting periods prior to enactment, and that not less than 75 percent of additional positions received must be in a primary care or a general surgery residency. Geriatrics is included in the definition of "primary care resident" at section 1886(h)(5)(H) of the Act.

We believe that, of all the medical specialties, geriatrics is the one specialty that is devoted primarily to the care of the elderly, including Medicare beneficiaries. As such, we are proposing to give special consideration to geriatric programs to meet the "fill rate" criterion for demonstrating the likelihood of filling FTE resident slots under section 5503. Geriatrics is not a separately approved training program; rather, it is a subspecialty of another specialty program. For example, there is a geriatrics subspecialty of family practice or internal medicine. We are proposing that, for the purposes of meeting the 85 percent fill rate criterion, we would allow hospitals that are starting a new geriatrics program or expanding an existing geriatric program to use the fill rate associated with the overall specialty program (rather than the fill rate for the geriatric subspecialty) to meet this demonstrated likelihood criterion.

Evaluation Criterion Three. *The hospital will use additional slots to establish a new or expand an existing primary care program with a demonstrated focus on training residents to pursue careers in primary care, rather than in nonprimary subspecialties of those primary care programs (for example, the hospital has an internal medicine program with a designated primary care track).* (3 Points) As stated previously, section 5503 places a particular emphasis on encouraging the growth in the number of primary care residents, and specifically, physicians who practice in primary care, rather than only completing a primary care residency as a prerequisite for further subspecialty training. Although this proposed Evaluation Criterion applies to any primary care specialty, according to the 2010-2011 ACGME Green Book, 30.1 percent of accredited internal medicine programs offer a primary care track. However, the ACGME does not have

separate standards for or does not separately accredit primary care tracks from categorical primary care programs. We understand that, particularly for internal medicine residents, these tracks are a way for graduating medical students who are interested in primary care to declare that interest early on, and in many cases, actually match into an internal medicine program with a primary care track through the National Residency Match Program. These residents may pursue their interest in primary care by choosing to do more electives in ambulatory and community-based settings throughout the 3 years of primary care training than residents with an interest in specialization might do. We believe that encouraging growth of these programs will increase the number of primary care practitioners. Therefore, we are proposing to give special consideration to hospitals that are applying for additional slots to start or expand a program(s) that particularly focuses on residents who wish to pursue careers in primary care, and we would prioritize among hospitals that are applying for slots in a primary care program(s) accordingly. One example of a hospital that demonstrates a focus on training residents to pursue careers in primary care is a hospital that has a primary care track in internal medicine. We are proposing that one way hospitals may qualify for a point under this evaluation criterion is by documenting that they are advertising that they have an internal medicine program with a primary care track in the March 2011 National Residency Match Program.

Evaluation Criterion Four. *The hospital will use all the additional slots to establish a new or expand an existing primary care residency program or general surgery program.* (5 Points) "Primary care resident" is defined at section 1886(h)(5)(H)

of the Act as a resident enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine, or osteopathic general practice. Section 1886(h)(8)(B)(ii)(II) of the Act states that not less than 75 percent of additional positions received must be in a primary care or a general surgery residency. Therefore, we are proposing to award 5 points to a hospital that goes beyond this minimum requirement, and documents that it will use all of the slots received for either primary care or general surgery programs.

Evaluation Criterion Five. *The hospital is located in a Primary Care HPSA.*- 2 Points. We believe this evaluation criterion is consistent with the goal of reducing the shortage of primary care physicians, and increasing access to care in underserved areas.

Evaluation Criterion Six. *The hospital is in a rural area (as defined under section 1886(d)(2)(D)(ii) of the Act) and is or will be on or after July 1, 2011, a training site for a rural track residency program (as specified under §413.79(k)), but is unable to count all of the FTE residents training in the rural track because the rural hospital's FTE cap is lower than its unweighted count of allopathic or osteopathic FTE residents as of portions of cost reporting periods on or after July 1, 2011*. (1 Point). We understand that there are some rural hospitals that serve as training sites for an urban hospital's rural training track. The residents in the rural track are counted in the urban hospital's FTE count, but because the rural training tracks are not necessarily considered "new" medical residency programs according to the regulations at §413.79(l), the rural hospital cannot receive an increase to its FTE caps under §413.79(e)(3) and, therefore, cannot receive direct GME and IME payments for training all or some of those residents. The rural

hospital may be training residents in excess of its FTE resident cap prior to July 1, 2011 and, therefore, cannot receive IME or direct GME payment for some or all of the FTEs in the rural training track, or it wishes to expand its rural training track above its FTE resident cap on or after July 1, 2011. We are proposing this evaluation criterion as a remedy to these scenarios to allow the rural hospital the possibility of receiving payment for FTEs in its rural training track.

We are proposing to use these criteria to evaluate the applications by hospitals for increases in their FTE resident caps that fall within each of the seven level priority categories. We are proposing to place each application in the appropriate priority level category based on a review of the information a hospital checks off on the proposed CMS Evaluation Form for each allopathic and osteopathic specialty program requested by the applicant hospital, and the corresponding requested FTE cap increase (the proposed form appears below). We propose to place all of these evaluation criteria on the Evaluation Form and to ask the hospital to check off which criteria on the form apply for each specialty program for which an FTE cap increase is requested. Based on the evaluation criteria checked off on the form, we are proposing to score each CMS Evaluation Form. The higher-scoring CMS Evaluation Form(s) for each applicant hospital within each level priority category would be awarded the FTE resident cap increases first. It is possible that a hospital may qualify for multiple points for the same program. For example, if a hospital would be applying for slots to start a primary care track within an internal medicine program, and also would be using all of the slots it receives in that internal medicine program, the hospital may receive points both for Evaluation Criterion Three

and Evaluation Criterion Four. Similarly, if a hospital would be applying for slots to start or expand a geriatrics program, and the additional slots would all be used for the geriatrics program, then the hospital may receive points for both Evaluation Criterion Two and Evaluation Criterion Four. Further, as specified by section 1886(h)(8)(E) of the Act, 70 percent of all positions are reserved to be distributed to qualifying hospitals that are in States with resident-to-population ratios in the lowest quartile, and 30 percent of the positions are reserved to go to hospitals that are located in States with HPSA population to State population ratios within the top 10 and to rural hospitals. As we described above, we are proposing to award the cap increases in the order of the seven specified level priority categories because, as a general rule, we believe hospitals that meet more than one of the statutory priorities should be awarded the increases in their FTE resident caps first before other hospitals. We also believe that hospitals that meet a higher statutory priority category should receive first consideration over hospitals that meet lower statutory priorities. That is the reason, for instance, we are proposing that the first, second, and third level categories give preference to hospitals located in States with resident-to-population ratios in the lowest quartile before considering hospitals that are only located in States with high Primary Care HPSA population to State population ratios or to hospitals that are only rural. Furthermore, in the case where, for example, Hospital A's application for a program falls within the Level Priority Category One, but scores no points on the evaluation criteria on the CMS Evaluation Form for that program, and Hospital B's application for a program falls within the Level Priority Category Two, and scored 5 points on the evaluation criteria on the CMS Evaluation Form for the program,

Hospital A would receive the section 5503 cap increase *before* Hospital B, because Hospital A qualified to be in the higher level priority category.

Thus, first level priority category hospitals that score highest on the evaluation criteria on the CMS Evaluation Form for a particular specialty program would receive the increases in their FTE resident caps first. For example, if Hospital D is a rural hospital that is located in Mississippi, thereby falling within the first level priority category, and Hospital D checks off on the CMS Evaluation Form that it has a Medicare utilization of 60 percent (5 points), is using all the slots to expand a primary care residency program (5 points), and is located in a Primary Care HPSA (2 points), Hospital D would receive a score of 12 points on the completed CMS Evaluation Form. We are proposing that we would first award FTE cap increases to hospitals whose CMS Evaluation Forms for a particular program receive the most points (if there are any), and then to those with successively fewer points within the level priority category. Hospital D would receive the increase in its FTE resident cap(s) requested on its application only after all the hospitals in the first level priority category whose applications receive 13 or more points are awarded their requests first. We are proposing to proceed through each level priority category accordingly, and only move on to distribute slots to hospitals in the next priority level category once all the qualifying applicants in the previous priority level category have received slots. Once we have distributed 70 percent of the slots to hospitals within States with resident-to-population ratios in the lowest quartile in accordance with the Priority Level Categories One through Three (or awarded increases to all qualified applicant hospitals located in States with resident to population ratios in the lowest

quartile), we are proposing to then distribute the remaining slots to hospitals in the fourth and fifth level categories. Because of this requirement that 70 percent of the slots be reserved for distribution to hospitals within States with resident-to-population ratios in the lowest quartile, it is possible that after first distributing slots to hospitals with the highest scores on their CMS Evaluation Form, if there are requests for slots by those hospitals which in the aggregate exceed the 70 percent of slots available, there may be some remaining qualifying hospitals within the same priority level category that receive the same score on the CMS Evaluation Form. Thus, we would have no way of distinguishing among these hospitals of equal rank. If this situation occurs, we are proposing to prorate the remaining amount of slots in the "70 percent" pool, and distribute an equal share of slots to these hospitals of equal rank. If a similar situation occurs within the "30 percent" pool, we also are proposing to prorate the remaining amount of slots in the "30 percent" pool, and distribute an equal share of slots to hospitals of equal rank.

For example, assume all applicant hospitals in the first and second level priority categories receive the requested increases in their FTE resident caps, and that we have awarded cap increases for all the third level priority category hospitals that scored 5 or above on their CMS Evaluation Forms for each residency program. We next evaluate hospital applications and accompanying CMS Evaluation Forms in the third Level Priority Category (The hospital is in a State whose resident-to-population ratio is within the lowest quartile) with fewer than 5 points and we find that there is only a sufficient number of resident slots remaining in the estimated "70 percent" pool to grant half of the

requests for slots from hospitals that scored 4 points. We are proposing to prorate all of the remaining FTEs among the 4-point CMS Evaluation Forms and accompanying applications in the third level priority category. Thus, after awarding slots to hospitals in the third level priority with at least 5 points, and to hospitals in the first two level priority categories, if we could have awarded a total of 200 FTE slots for direct GME and 185 FTE slots for IME to only 50 percent of the 4-point CMS Evaluation Forms in the third level priority category (at the point that the estimated "70 percent" pool of FTE slots is spent), we are proposing to divide all of the 200 FTE slots remaining in the 70 percent pool for direct GME and 185 FTE slots for IME among all of the 4-point CMS Evaluation Forms and accompanying applications in that third priority category, no matter what level of FTE resident cap increase was requested on the individual hospital's application, but not to exceed the number of slots a hospital requested for IME and direct GME respectively.

We are also considering another possible scenario that could occur with respect to hospitals that fall into the Second Level Priority Category: The hospital is in a State whose resident-to-population ratio is within the lowest quartile, AND is either in a State whose Primary Care HPSA to population ratio is in the top 10 States, or it is located in a rural area, or is an urban hospital and has or will have as of July 1, 2010, a rural training track. Because a hospital in this second level priority category is located both in a State whose resident-to-population ratio is within the lowest quartile, AND is either in a State whose Primary Care HPSA to population ratio is in the top 10 States, or it is located in a rural area, we believe that its request for additional slots must first be fulfilled from the

"70 percent pool." However, if there are insufficient slots in the "70 percent pool" to satisfy the requests of all otherwise qualified applicants in the second level priority category, then, rather than immediately prorating the remaining slots in the "70 percent pool" among the applicable hospitals in the second level priority category, we are proposing to draw from the "30 percent pool" to grant the full FTE cap increases (as applicable) to qualifying hospitals in the second level priority category.

Alternatively, although unlikely, we recognize that the reverse situation may occur, where there may not be a sufficient number of qualified applicants or requests for FTEs in order to distribute at least 70 percent of the slots hospitals located in the 13 States whose resident-to-population ratios are in the lowest quartile (priority level categories one through three). Should this occur, we are proposing to begin evaluating applications from the next category of qualifying hospitals (that is, those located in States that are among the top 10 States for Primary Care HPSA to population ratios, and rural hospitals—priority level categories four and five), and potentially distribute more than 30 percent of the slots to hospitals in those latter categories.

We recognize the complexity of the proposed evaluation process for the award of increases in hospital's FTE resident caps under section 1886(h)(8)(B) of the Act. Therefore, we have included the following examples depicting the proposed procedures:

Example 1

Hospital H is an urban hospital located in a State that is in the lowest quartile for resident-to-population ratios. Hospital H can demonstrate the likelihood that it will fill the requested five FTEs resident slots for direct GME and IME for expanding a geriatric

program because it is currently training a number of FTE residents that exceeds both of its FTE caps, and has attached to its application for the increase a copy of Hospital H's past three Medicare cost reports (as filed or audited, whichever is most recent and available), which documents on Worksheet E, Part A, Worksheet E-3, Part IV, and Worksheet E-3, Part VI that, according to the resident counts and the FTE resident caps, Hospital H is training residents in excess of its caps. Hospital H is also located in a Primary Care HPSA (but is not located in a State that is among the top 10 States in terms of its Primary Care HPSA population to State population ratio).

We would evaluate Hospital H's application as follows: Hospital H is in the third Level Priority Category (The hospital is in a State whose resident-to-population ratio is within the lowest quartile), and receives a score of 12 (expanding a geriatrics program-Evaluation Criterion Two—5 points, using all slots for a primary care residency program-Evaluation Criterion Four—5 points, and is located in a Primary Care HPSA-Evaluation Criterion Five—2 points).

Example 2

Hospital J is a rural hospital located in Montana. Hospital J is a rotation site for an urban hospital's family practice rural track program, but is unable to count all of the FTE residents training in the rural track because the rural hospital's FTE cap is lower than its unweighted count of allopathic or osteopathic FTE residents as of portions of cost reporting periods on or after July 1, 2011. The rural hospital wishes to expand the number of FTE residents training in the family practice rural track. The rural hospital

also wishes to serve as a training site for one pediatrics resident in a pediatrics program that already exists at the urban hospital (that is, it is not a new pediatrics program).

Hospital J would need to submit two CMS Evaluation Forms; one for family practice and another for pediatrics, and we would evaluate each accordingly. Both requests would put the hospital in the second level priority category (The hospital is in a State whose resident-to-population ratio is within the lowest quartile, AND is either in a State whose Primary Care HPSA to population ratio is in the top 10 States, or it is located in a rural area, or is an urban hospital and has or will have as of July 1, 2010, a rural training track), and it can demonstrate the likelihood of filling the slots (because it is already over its FTE caps based on the family medicine residents it is training in the rural track, and together with the urban hospital, it has requested from the ACGME accreditation to expand the number of family practice residents training in the rural track and to receive a pediatrics resident). For the family practice request, Hospital J would receive 5 points under Evaluation Criterion Four because all the slots it is requesting (that is, family practice and pediatrics) are for primary care programs, and it would receive 1 point under Evaluation Criterion Six because it is requesting the family practice slots for its rural training track, for a total of 6 points for the family practice request. For the pediatrics request, Hospital J would be placed in the second Priority Level Category, and receives 5 points under Evaluation Criterion Four because all the slots it is requesting (that is, family practice and pediatrics) are for primary care programs.

15. Exception If Positions Are Not Redistributed by July 1, 2011

Section 1886(h)(8)(E)(iii) of the Act states that in the case where, by July 1, 2011, the Secretary "does not distribute positions to hospitals," the Secretary shall distribute such positions to other hospitals in accordance with the considerations in redistribution specified at section 1886(h)(8)(C) of the Act (that is, the demonstrated likelihood of filling the slots and whether the hospital has a rural training track), and the priority for certain areas specified at section 1886(h)(8)(D) of the Act (that is, whether the hospital is located in a State with a resident-to-population ratio in the lowest quartile, whether the hospital is located in a State that is in top 10 States in terms of Primary Care HPSA population to State population, and whether the hospital is rural). We believe that the phrase "does not distribute positions to hospitals" contemplates the scenario where there would be more slots available than the amount that qualifying hospitals requested, and therefore, CMS would be left with slots in the distribution pool as of July 1, 2011. The Secretary is directed to initiate another round of applications after July 1, 2011, in which hospitals that could demonstrate that they could use the slots would apply and possibly receive a portion of the remaining slots, until all the slots in the pool are redistributed. Should the situation arise where there are unused slots available as of July 1, 2011, we would propose a process for redistributing those slots "in accordance with the considerations in redistribution specified at section 1886(h)(8)(C)." We would then alert the public through another round of notice and comment rulemaking to establish the application timeframe, criteria, process and other relevant information at that time.

16. Application of Direct GME PRAs for Primary Care and Nonprimary Care Residents and Conforming Changes for the IME Multiplier

Section 1886(h)(8)(G) of the Act states that, "With respect to additional residency positions in a hospital attributable to the increase provided under this paragraph, the approved FTE per resident amounts are deemed to be equal to the hospital per resident amounts for primary care and nonprimary care computed under paragraph (2)(D) for that hospital." Hospitals that receive increases in their FTE resident caps under section 1886(h)(8)(B)(i) will receive direct GME payments associated with those FTE residents in the same manner as they receive direct GME payments for their other (non-section 422) FTE residents, that is, using the primary care PRA that is reported on Worksheet E-3, Part IV, line 3.23, and the nonprimary care PRA reported on line 3.17 of the same worksheet. This provision in section 5503 differs from section 422 in that hospitals that received additional slots under section 422 receive direct GME payment for FTE residents attributable to those slots using a single locality-adjusted national average PRA (42 CFR 413.77(g)), and the payment determination is made on Worksheet E-3, Part VI. Thus, if a hospital received additional slots under section 422, and they train a number of residents that is sufficient to require them to count FTE residents under those slots, the hospital will continue to receive direct GME payment for those slots using the locality-adjusted national average PRA. However, we are proposing that a hospital that receives additional slots under section 5503 would be paid for FTE residents counted under those slots using the same primary care and nonprimary PRAs for which payment is made for FTE residents subject to the 1996 FTE cap. We are expecting to revise Worksheet E-3,

Part IV to add a line on which hospitals would report the number of FTEs by which the hospital's FTE caps were increased for direct GME slots received under section 5503. To create a hospital's total adjusted direct GME FTE cap, the increase granted under section 1886(h)(8)(B)(i) would be added to the 1996 direct GME FTE cap and would include any applicable new program adjustment received under §413.79(e), and any applicable adjustments for the cost reporting period due to a Medicare GME affiliation agreement. In a given cost reporting year, we are proposing that a hospital would only count FTE residents under its direct GME section 422 cap slots on Worksheet E-3, Part VI if the number of unweighted allopathic and osteopathic residents it is training exceeds the total adjusted direct GME cap (including the section 5503 slots) on Worksheet E-3, Part IV.

In addition, with respect to the IME adjustment, we are proposing that a hospital that receives an increase in its FTE cap under section 1886(h)(8)(B)(i) will count FTE residents under those slots, and payment will be made with respect to residents counted under those slots, using the same IME multiplier for which payment is made for FTE residents subject to the 1996 FTE cap (that is, currently a multiplier of 1.35). This is because section 1886(d)(5)(B)(x) of the Act, as added by section 5503(b)(2), states, "For discharges occurring on or after July 1, 2011, insofar as an additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(8)(B), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions." This provision in section 5503 differs from section 422 in that hospitals that received

additional slots under section 422 receive IME payment for FTE residents counted under those slots using a special multiplier of 0.66 (42 CFR 412.105(e)(2)), and the payment determination is made on Worksheet E-3, Part VI. We also are expecting to revise Worksheet E, Part A to add a line in which applicable hospitals would report the amount of additional IME slots received under section 5503. To create a hospital's total adjusted IME FTE cap, this additional amount would be added to the 1996 IME FTE cap, any applicable new program adjustment received under §413.79(e), and any applicable adjustments for the period due to a Medicare GME affiliation agreement. In a given cost reporting year, we are proposing that a hospital would only use its IME section 422 cap slots on Worksheet E-3, Part VI if the number of unweighted allopathic and osteopathic residents it is training exceeds the total adjusted IME cap (including the section 5503 slots) on Worksheet E, Part A. Finally, under section 422 of Pub. L. 108-173, hospitals that were members of the same Medicare GME affiliated group on or after July 1, 2005, and that received additional FTE cap slots under section 422 are precluded from including those additional section 422 slots in the aggregate affiliated cap. This is in part because section 422 specified that a hospital would receive direct GME and IME payments for additional slots awarded under section 422 with rates that were different from the non-section 422 cap slots, and tracking the different direct GME and IME payment rates associated with FTE residents that are counted as a result of the section 422 cap increases and those that were not would be extremely difficult for the Medicare contractors. In addition, in order to qualify for additional slots under section 422, the hospitals had to document a need for those slots. Similarly, under section 5503, we are

proposing that hospitals that receive additional slots under section 5503 cannot use these slots as part of the aggregate cap in a Medicare GME affiliation agreement. This is because we believe that once a hospital has demonstrated that it truly needs the additional slots, has made the effort to carefully document that it will fill those slots within three years, and once we have determined that the characteristics of the hospital and its training program warrant an increase in the hospital's FTE resident caps under section 1886(h)(8)(B)(i), we do not believe it would be appropriate for the hospital to transfer those positions to another hospital, albeit temporarily, under the terms of a Medicare GME affiliation agreement. To do so would be to undermine the goals and specifications for the redistribution of residency positions as set forth under section 5503.

We note that section 1886(h)(8)(B) of the Act, which addresses the increases in hospitals' FTE resident caps, makes no reference to section 1886(h)(4)(G) or 1886(d)(5)(B)(vi)(II) of the Act, which are the provisions concerning the rolling average count of FTE residents. Furthermore, there is no mention of section 1886(d)(5)(B)(vi)(I) of the Act, the provision regarding the cap on the IME resident-to-bed ratio, in section 1886(h)(8)(B) of the Act either. That is, the statute does not provide for an exclusion from application of the rolling average for residents counted as a result of FTE cap increases under section 1886(h)(8)(B)(i) of the Act, nor does the statute exempt the residents counted pursuant to FTE cap increases under section 1886(h)(8)(B)(i) from the application of the cap on the IME resident-to-bed ratio. In light of the absence of a specific directive in section 1886(h)(8)(B)(i) of the Act exempting those residents from application of the rolling average for direct GME and IME, and the cap on the IME

resident-to-bed ratio, and with no apparent reason to treat residents counted as a result of the FTE cap increases under section 1886(h)(8)(B) of the Act differently, we are proposing to require that if a hospital increases its direct GME or IME FTE count of residents under an increase in the hospital's FTE resident cap under section 1886(h)(8)(B)(i) of the Act, those FTE residents would be immediately subject to the rolling average calculation and the cap on the IME resident-to-bed ratio. Furthermore, we believe that, given potentially significant shifts of FTE resident positions among hospitals as a result of section 1886(h)(8) of the Act, the inclusion of FTE residents counted as a result of FTE cap increases under section 1886(h)(8)(B)(i) of the Act in the rolling average would introduce a measure of stability and predictability, and mitigate radical shifts in GME payments from period to period.

17. Other Issues Related to a Request for Increase in the FTE Caps under Section 5503

- Rural Hospitals or Urban Nonteaching Hospitals

Rural hospitals may receive an adjustment to their FTE caps for establishing a new residency program under §413.79(e)(1)(iii)) of the existing regulations at any time. Therefore, if a rural hospital is interested in starting a new program, or interested in participating in training residents in a new program on or after July 1, 2011, it need not apply for slots under section 5503 for that new program. If a rural hospital seeks to expand an existing program, and does not have sufficient space under its existing FTE caps to cover those additional residents, the rural hospital may apply for an increase to its FTE caps under section 5503. Similarly, an urban hospital may request additional slots under section 5503 for the purpose of expanding an

existing program. A hospital, rural or urban, that is not yet a teaching hospital and does not have a cap established, may not apply for a permanent adjustment to their FTE caps under section 5503 since a non-teaching hospital may apply for a permanent cap adjustment under current Medicare regulations at §413.79(e). Also, if an urban non-teaching hospital becomes a teaching hospital because it begins to serve as a rotating site for another hospital's existing program, it may apply for additional slots under section 5503, which would not preempt the hospital from later getting a new cap adjustment under §413.79(e) for starting a new program.

- Closed Teaching Hospitals

We note that under section 5506 of P.L. 111-148, as explained further in section XVII.E. of this proposed rule, the FTE resident caps of teaching hospitals that close on or after March 23, 2008 are to be redistributed to other qualifying hospitals according to specific criteria. Assuming a teaching hospital closed recently, it is possible that based on the closed teaching hospital's three most recent cost reporting periods ending prior to March 23, 2010, its FTE resident caps could be subject to reduction under section 5503. However, so as to avoid duplication of FTE resident slots in the redistribution processes under sections 5503 and 5506, we are proposing that if a hospital closes on or after March 23, 2008, then its FTE resident cap slots would *not* be redistributed under section 5503, but would be reserved for redistribution under section 5506.

- Requirements for Hospitals That Receive Additional Slots under Section 5503

Section 1886(h)(8)(B)(ii) of the Act, as added by section 5503(a)(4) of the Affordable Care Act, specifies requirements and thresholds that a hospital that applies for and receives additional slots effective July 1, 2011 must meet in order to retain those slots. Under section 422 of Pub. L. 108-173, hospitals that received additional slots were not held accountable for meeting any requirements once those slots were received effective July 1, 2005, nor did section 422 require that CMS conduct any subsequent reviews of the hospitals that received the slots in order to determine that the hospitals were meeting certain thresholds. However, section 1886(h)(8)(B)(i) of the Act, as added by section 5503 of the Affordable Care Act specifies requirements that a hospital that receives an increase in its FTE resident caps under section 1886(h)(8)(B)(i) must meet, at least for a 5-year period beginning on and after July 1, 2011, and section 1886(h)(8)(B)(iii) directs the Secretary to reduce the FTE caps of the hospital by the same number of FTE residents by which the hospital's FTE caps were increased if the hospital fails to meet these requirements. Specifically, section 1886(h)(8)(B)(ii) of the Act states, "a hospital that receives an increase in the otherwise applicable resident limit under this subparagraph shall ensure, during the 5-year period beginning on the date of such increase, that—

(I) The number of full-time equivalent primary care residents, as defined in paragraph (5)(H) (as determined by the Secretary), excluding any additional positions under subclause (II), is not less than the average number of full-time equivalent primary care residents (as so determined) during the 3 most recent cost reporting periods ending prior to the date of enactment of this paragraph; and

(II) not less than 75 percent of the positions attributable to such increase are in a primary care or general surgery residency (as determined by the Secretary).

The Secretary may determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period."

Section 1886(h)(5)(H) of the Act defines "primary care resident" as a resident enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine, or osteopathic general practice. We are proposing that a hospital that is applying to receive additional slots would have to submit data from the 3 most recent cost reporting periods ending before March 23, 2010 (the date of enactment) on the number of unweighted FTE residents in these primary care programs. We note that this primary care average is based on the hospital's total FTE count that would otherwise be allowable in absence of the FTE cap; if a hospital is training FTE residents in excess of its FTE caps, it would still determine the 3-year average based on the total number of unweighted primary care FTE residents. A total primary care FTE count, one for IME and one for direct GME, is sufficient for the hospital for each of these 3 cost reporting periods; a hospital need not report these data by specialty. However, we note that, currently, the Medicare cost report does not track a hospital's number of primary care residents. For direct GME, on Worksheet E-3, Part IV, line 3.19, the hospital's number of weighted primary care and OB/GYN residents is reported. Thus, if a hospital trains OB/GYN residents in addition to primary care residents, we are proposing that the OB/GYN count must be subtracted

from the number reported on line 3.19 of Worksheet E-3, Part IV for the hospital's 3 most recent cost reporting periods ending before March 23, 2010. This would produce a weighted FTE count for direct GME. In any case, the source documentation for these data is the rotation schedules for the applicable years. For IME, on Worksheet E, Part A, there is no line that currently records the number of primary care residents, as the distinction between primary care and non-primary care residents is only necessary in the direct GME payment formula (due to the use of a primary care and OB/GYN PRA and a nonprimary care PRA for certain years).

Therefore, we are proposing that the applicant hospital must develop from its rotation schedules three IME FTE primary care counts to correspond to its three most recent cost reporting periods ending before March 23, 2010. As part of its application, we are proposing that the hospital must include the documentation that it used to arrive at its direct GME and IME primary care FTE counts, including a copy of Worksheet E-3, Part IV for direct GME, and if the hospital has an OB/GYN program, the rotation schedules corresponding to the three most recent cost reporting periods ending prior to March 23, 2010 for OB/GYN, and the rotation schedules for all primary care residency programs used to establish the IME primary care FTE count corresponding to the three most recent cost reporting periods ending prior to March 23, 2010. Although we have considered proposing that a hospital may demonstrate that it is complying with the requirement to maintain the primary care average with only a single unweighted FTE count, rather than one FTE count for direct GME and one FTE count for IME, we believe that we need to propose to require documentation from both a direct GME and an IME

FTE count because section 5503 of the Affordable Care Act amended section 1886(d)(5)(B)(v) of the Act to make the entire section 1886(h)(8), of which maintenance of this primary care average is a part, applicable for purposes of IME. Thus, both section 1886(h) of the Act for direct GME and section 1886(d)(5)(B) of the Act for IME are equally impacted by section 5503. Furthermore, we are proposing that the FTE counts for IME and direct GME used to derive these primary care averages are subject to audit by the Medicare contractors, and that, as part of reviews or audits performed by the Medicare contractors in accordance with their normal audit plans, the Medicare contractors would check whether a hospital is maintaining its primary care average in each of the cost reports in the 5-year period as early as tentative settlement of those five respective cost reports, and may take prompt action accordingly to adjust a hospital's FTE caps and direct GME and IME interim payments.

In addition to maintaining this average number of primary care residents, section 1886(h)(8)(B)(ii)(II) of the Act also requires that a hospital that receives an increase to its FTE resident caps under section 1886(h)(8)(B)(i) must ensure that 75 percent of those slots are used to train primary care or general surgery residents. A hospital that applies for additional slots may or may not already train at least 75 percent or more of its residents in primary care or general surgery programs. At a minimum, the applicant hospital is required to maintain the average number of FTE primary care residents that it trained during the three most recent cost reporting periods ending prior to March 23, 2010. Further, we are proposing that in addition to the primary care residents used to maintain the primary care average, the applicant hospital must separately ensure

that at least 75 percent of the increased FTE cap slots it receives are used to count FTE residents in primary care or general surgery. We are proposing that the hospital must be able to document that, during each of the five years in the five-year period of July 1, 2011 to June 30, 2016, for IME and direct GME respectively, and for each cost report during those five years, that not only is it maintaining its primary care average, but that 75 percent of the increased FTE cap slots that it received are being used to count residents training in primary care or general surgery programs. For example, Hospital A has a June 30 fiscal year end, an FTE cap of 100 FTEs, and a total FTE count of 110. In its three most recent cost reports ending prior to March 23, 2010 (fiscal year end June 30, 2009, June 30, 2008, and June 30, 2007), Hospital A was training 60 primary care FTE residents, 50 primary care FTE residents, and 40 primary care FTE residents respectively. The average number of primary care FTE residents during those three years is 50. Hospital A applied for and received 10 additional FTE cap slots under section 5503. Beginning July 1, 2011, for each cost report ending June 30, 2012, June 30, 2013, June 30, 2014, June 30, 2015, and June 30, 2016, Hospital A must ensure that it does not train less than 50 primary care FTE residents, and it must ensure that it trains an *additional* 7.5 FTEs of the 10 slots it receives in either primary care or general surgery. In another example, Hospital B has a December 31 fiscal year end, an FTE cap of 10 FTEs, and a total FTE count of 12. In its 3 most recent cost reports ending prior to March 23, 2010 (fiscal year end December 31, 2009, December 31, 2008 and December 31, 2007), Hospital A was training 12 primary care FTE residents in each of the 3 years. The average number of primary care FTE residents is 12. Hospital B applied

for and received 4 additional FTE cap slots under section 5503. Beginning July 1, 2011 and ending June 30, 2016, Hospital B must ensure that it does not train less than 12 primary care FTE residents, and it must ensure that it trains an *additional* 3 FTEs of the 4 slots it receives in either primary care or general surgery. We are proposing that the Medicare contractors would check whether a hospital is maintaining this 75-percent threshold as part of reviews or audits performed by the Medicare contractors in accordance with their normal audit plans in the 5-year period as early as tentative settlement of those five respective cost reports, and may take action accordingly to adjust a hospital's FTE resident caps and direct GME and IME interim payments.

It is possible that there are hospitals that are not currently training, nor have they trained in any of their three cost reporting periods ending prior to March 23, 2010, any primary care residents at all, but that such hospitals are applying for an increase to their FTE caps for a new primary care or general surgery program that they would like to start. Such hospitals would have a primary care average of zero. Because the intent of section 5503 is to try to increase the number of primary care (or general surgery) residents in training, we are proposing that such hospitals would be able to apply for additional slots under section 5503. Should such a hospital receive an FTE cap increase, we are proposing that 75 percent of the increased FTE cap slots must be used to count FTE residents in either primary care or general surgery. We are proposing that a hospital is required to document in <u>each</u> of the 5 years that it has maintained the primary care average and that at least 75 percent of the slots it receives is used for training either primary care and/or general surgery residents rather than only once at the end of the 5-

year period. As explained more fully below, if a hospital has not met these requirements, we believe it would be less disruptive financially and administratively to a hospital if we make the adjustment to the hospital's FTE resident caps under section 1886(h)(8)(B)(iii)(I) and recover any overpayment after 1 year rather than after the conclusion of the full 5 year monitoring period under section 1886(h)(8)(B)(ii).

Section 1886(h)(8)(B)(ii) of the Act also states that "The Secretary may determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period" (emphasis added). We are proposing that the "5-year period beginning on the date of such increase" is July 1, 2011 through June 30, 2016, because the effective date of section 5503 is for portions of cost reporting periods beginning on or after July 1, 2011. Thus, it is during this 5-year period that an "average number of full-time equivalent primary care residents" must be maintained, and that 75 percent of the additional slots must be trained in primary care or general surgery, for IME and direct GME respectively. However, the Secretary is given some discretion as to how and when she determines whether a hospital is meeting or has met the requirements "during such 5-year period." Although we believe that the 5-year period must be within July 1, 2011 through June 30, 2016, we believe we have flexibility to determine which cost reporting periods within that 5-year period we may use to assess whether the hospital is consistently meeting the required criteria. For the sake of administrative simplicity, on behalf of hospitals and the Medicare contractors, we are proposing that the Medicare contractors, in accordance with their normal audit plans, would make assessments based

on a hospital's fiscal year when possible, such that the Medicare contractors could make a first assessment for an initial "short" period, then annually as each of the hospital's fiscal year ends until there is another final "short" assessment period that starts after the provider's last fiscal year end within the 5-year window and runs through June 30, 2016. If a hospital has a June 30 fiscal year end, we are proposing that the Medicare contractor could assess whether the hospital is meeting the required criteria five times, starting with its cost reporting period beginning on July 1, 2011, and ending with its fifth cost reporting period that starts on July 1, 2015 (and ending June 30, 2016). However, for hospitals that have a fiscal year end of other than June 30, we are proposing that the Medicare contractors could assess whether the hospital met the requirements for the portion of its cost reporting period that occurs after July 1, 2011, its subsequent full cost reporting periods, and then ending with the portion of the cost reporting period prior to June 30, 2016. In other words, we are proposing that the hospital would be considered to meet the required criteria in "Year 1" if it meets the requirements based on an annualized FTE count from July 1, 2011 through the end of its cost reporting period; in each of years 2 through 4, it must meet the requirements based on its next 3 cost reporting periods; and in year 5, it must meet the requirements based on an annualized FTE count from the first day of its cost reporting period through June 30, 2016 (which is the last day on which a hospital has any obligation to meet these requirements). For example, assume Hospital C has a September 30 fiscal year end, and receives 16 additional slots under section 5503, and has a primary care average of 30 FTE residents. We are proposing that during the period of July 1, 2011 through June 30, 2016, Hospital C must demonstrate that it is

training at least 75 percent of its 16 slots in primary care or general surgery (that is, 12 slots), and that it maintains a primary care FTE count of 30, as follows:

Year 1 – July 1, 2011 to September 30, 2011, with an annualized count of 3 (that is, 12 divided by 4) additional FTEs in primary care/general surgery, and an annualized count of 7.5 (that is, 30 divided by 4) FTEs training in primary care residency programs.

Year 2 – October 1, 2011 to September 30, 2012, with 12 FTEs in primary care/general surgery, and 30 FTEs in primary care programs.

Year 3 – October 1, 2012 to September 30, 2013, with 12 FTEs in primary care/general surgery, and 30 FTEs in primary care programs.

Year 4 – October 1, 2012 to September 30, 2014, with 12 FTEs in primary care/general surgery, and 30 FTEs in primary care programs.

Year 5 – October 1, 2014 to September 30, 2015, with 12 FTEs in primary care/general surgery, and 30 FTEs in primary care programs.

Year 6 -- October 1, 2015 to June 30, 2016, with an annualized count of 9 additional FTEs in primary care/general surgery, and an annualized count of 22.5 FTEs training in primary care residency programs.

We are proposing to reserve the right to assess as many times as necessary in the 5-year period that a hospital is meeting the required criteria. Furthermore, if a Medicare contractor determines during an audit that a hospital did not meet the requirements during, for example, the second year, the contractor could go back and audit the first year (full, or short period), and make a retroactive adjustment. We also understand that we should consider that hospitals might not immediately fill all the slots they receive,

particularly because they are only required to demonstrate the likelihood of filling the slots within the first three cost reporting periods beginning on or after July 1, 2011. Accordingly, in the preceding example in which Hospital C was awarded 16 slots and has a September 30 fiscal year end, assume it only added 2 actual residents immediately on July 1, 2011. Two residents equate to 0.5 FTE for the 3-month period of July 1, 2011 to September 30, 2011. Seventy five percent of 0.5 FTE equals 0.375. We are proposing that at least 0.375 of the new FTEs added for the period of July 1, 2011 to September 30, 2011 must be in primary care or general surgery in order to meet the requirement in "Year 1."

In a case where the Medicare contractor determines that a hospital did not meet the requirements in a cost reporting year within the 5-year time period, section 1886(h)(8)(B)(iii) of the Act states that "the Secretary shall—

(I) Reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph; and

(II) Provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph." Hospitals have different fiscal year ends and are subject to different audit schedules, which may occur several years after a hospital's cost report is submitted. Therefore, even though we are proposing that the Medicare contractors may make adjustments to a hospital's direct GME and IME payments as early as tentative settlement, it may be several years after June 30, 2016 before CMS determines the exact number of reductions, if any, that are applied to the FTE caps of hospitals that received additional slots, but that failed to meet the

requirements under section 1886(h)(8)(B)(ii) of the Act, discussed above. However, once we have determined the number of slots available for a second redistribution, we would distribute them "in accordance with the requirements of this paragraph." That is, we would distribute the slots to hospitals that applied under this first redistribution and that qualified to receive the slots they requested, but for whom we did not have sufficient slots in the "pool" to grant them the full number of FTE slots that they requested. As discussed above in section XVII.D. of this proposed rule, because of the requirement that 70 percent of the slots be redistributed to hospitals within States with resident-to-population ratios in the lowest quartile, it is possible that, after first distributing slots to hospitals with the highest scores on their CMS Evaluation Form, there may be some remaining qualifying hospitals within the same priority level category that receive the same score on the CMS Evaluation Form. Thus, we would have no way of distinguishing among these hospitals of equal rank. If this situation occurs, we are proposing to prorate the remaining amount of slots in the "70 percent" pool, and distribute an equal share of slots to these hospitals of equal rank. If a similar situation occurs within the "30 percent" pool, we also are proposing to prorate the remaining amount of slots in the "30 percent" pool and distribute an equal share of slots to hospitals of equal rank. Accordingly, in the event that there is a second redistribution process pursuant to section 1886(h)(8)(B)(iii)(II), we are proposing to distribute the slots in the "pool" (created by the failure of one or more hospitals to meet the criteria specified under section 1886(h)(8)(B)(ii)) to those hospitals that did not receive all of the slots for which they technically qualified, and for which we had to prorate under the first redistribution. If we

have sufficient slots to fully satisfy the original requests of those qualifying hospitals, we would assign them the difference between the prorated amount awarded under the first redistribution and the amount of slots they requested on their original application (assuming they actually otherwise qualified for all the slots they requested). In other words, we would go back to the original applications and continue to assign slots to those hospitals that originally qualified to receive slots under section 5503, but for which we did not have sufficient slots to satisfy their requests. We are proposing to assign the additional slots in the same priority order as under the first redistribution process under section 5503, resuming where we left off, until all the slots have been distributed. After such point, there would be no further harvesting of slots or redistribution under section 5503.

We are proposing to add new regulations at §412.105(f)(1)(iv)(C)(*2)* for IME and at §413.79(n) for direct GME to reflect our proposals regarding hospitals receiving increases to their FTE resident caps under section 5503, and the requirements that hospitals must meet in order to keep those FTE slots, and not be subject to a removal of those FTE slots during the 5-year period of July 1, 2011 through June 30, 2016.

- No Administrative or Judicial Review

Section 5503(a)(3) of the Affordable Care Act amended section 1886(h)(7)(E) of the Act by adding “or paragraph (8)” such that section 1886(h)(7)(E) of the Act now specifies that "There shall be no administrative or judicial review under section 1869, 1878, or otherwise, with respect to determinations made under this paragraph or paragraph (8)." As stated in the preceding section regarding reference cost reports that

are under appeal, we believe the fact that Congress included this language clearly means that the Congress intended for our determination with regard to FTE resident cap reductions under section 1886(h)(8)(A) to be final, and not subject to appeal. Because of this statutory language, together with the requirement that all reductions and increases in FTE resident caps be made effective July 1, 2011, we do not believe it would be appropriate to allow hospitals (or CMS) to appeal determinations concerning the FTE cap reductions or the FTE cap increases) under section 1886(h)(8) of the Act. In addition, as indicated previously, we believe that Congress intended this provision to be implemented fairly, but efficiently, avoiding the delays and uncertainty that would be produced by an appeals process. Furthermore, we note that, as explained previously in this preamble, as was done under section 422 of Public Law 108-173, Medicare contractors will provide hospitals with a time-limited opportunity to review cap reduction determinations for possible technical errors before they are finalized.

ADDENDUM

Trainees in Osteopathic Programs as Reported - By State 2008-2009

State	Interns		Residents		Total	
	Programs	Trainees	Programs	Trainees	Programs	Trainees
Alaska	1	3	0	0	1	3
Arizona	3	15	7	30	10	45
Arkansas	1	0	1	3	2	3
California	6	64	23	112	29	176
Colorado	1	0	0	0	1	0
Connecticut	1	10	1	3	2	13
Delaware	1	12	1	6	2	18
Florida	13	111	38	182	51	293
Georgia	3	5	3	3	6	8
Illinois	15	77	36	184	51	261
Indiana	3	8	3	12	6	20
Iowa	2	8	3	21	5	29
Kansas	1	3	1	3	2	6

State	Interns		Residents		Total	
	Programs	**Trainees**	**Programs**	**Trainees**	**Programs**	**Trainees**
Kentucky	6	16	7	15	13	31
Maine	4	14	9	42	13	56
Massachusetts	3	11	2	3	5	14
Michigan	24	338	174	858	198	1196
Minnesota	1	0	1	0	2	0
Mississippi	0	0	1	0	1	0
Missouri	5	24	21	90	26	114
Nevada	1	25	4	23	5	48
New Hampshire	1	4	0	0	1	4
New Jersey	9	83	48	236	57	319
New Mexico	1	1	1	4	2	5
New York	21	191	52	298	73	489
North Carolina	2	7	2	7	4	14
North Dakota	1	0	0	0	1	0
Ohio	17	168	97	397	114	565
Oklahoma	4	54	25	135	29	189
Oregon	1	0	6	0	7	0
Pennsylvania	43	282	97	455	140	737
Rhode Island	0	0	2	0	2	0
South Carolina	1	5	1	3	2	8
Tennessee	2	2	0	0	2	2
Texas	9	39	20	62	29	101
Virginia	5	16	9	30	14	46
Washington	0	0	1	0	1	0
West Virginia	8	43	18	53	26	96
Wisconsin	2	5	2	16	4	21
Wyoming	1	1	1	3	2	4
Total	**223**	**1,645**	**718**	**3,289**	**941**	**4,934**

Source: The American Osteopathic Association

Draft CMS Evaluation Form

As Part of the Application for the Increase in a Hospital's FTE Cap(s) under Section 5503 of the Affordable Care Act

Directions: Please fill out the information below for each residency program for which the applicant hospital intends to use the increase in its FTE cap(s). The applicant hospital is responsible for complying with the other requirements listed in the CY 2011 Hospital Outpatient Prospective Payment System Final Rule with Comment Period in order to complete its application for the increase in its FTE cap(s) under section 5503 of The Affordable Care Act, Pub. L. 111-148.

NAME OF HOSPITAL: _____

MEDICARE PROVIDER NUMBER: _____

NAME OF MEDICARE CONTRACTOR: _____

NAME OF SPECIALTY TRAINING PROGRAM: **_____**

(Check one): □ Allopathic Program □ Osteopathic Program

NUMBER OF FTE SLOTS REQUESTED FOR PROGRAM:

Direct GME: _____ IME: _____

Section A: Demonstrated Likelihood of Filling the FTE Slots

(Place an "X" in the box for the applicable criterion and subcriteria.)

A1: Demonstrated Likelihood Criterion 1. The hospital does not have sufficient room under its FTE cap for a new residency program that it intends to establish on or after July 1, 2011 (that is, a newly approved program that begins training residents at any point within the hospital's first three cost reporting periods beginning on or after July 1, 2011).

(1) Hospital will establish this newly approved residency program. **(The hospital must check at least one of the following, if applicable.)**

☐ Application for approval of the new residency program has been submitted to the ACGME, AOA or the ABMS by December 1, 2010. **(The hospital must attach a copy.)**

☐ The hospital has submitted an institutional review document or program information form concerning the new program in an application for approval of the new program by December 1, 2010. **(The hospital must attach a copy.)**

☐ The hospital has received written correspondence from the ACGME, AOA or ABMS acknowledging receipt of the application for the new program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit). **(The hospital must attach a copy.)**

(2) Hospital will likely fill the slots requested. **(The hospital must check at least one of the following, if applicable.)**

☐ The hospital does not have sufficient room under its FTE cap, and the hospital's existing residency programs had a resident fill rate of at least 85 percent in each of program years 2007 through 2009. **(The hospital must attach documentation.)**

☐ The hospital does not have sufficient room under its FTE cap, and the specialty program for which the hospital is applying has a resident fill rate either nationally, within the State, or within the CBSA in which the hospital is located, of at least 85 percent. **(The hospital must attach documentation.)**

☐ A2: Demonstrated Likelihood Criterion 2. The hospital does not have sufficient room under its FTE cap, and the hospital intends to use the additional FTEs to expand an existing residency training program within the hospital's first three cost reporting periods beginning on or after July 1, 2011.

☐ (1) Hospital intends to expand an existing program. **(The hospital must check at least one of the following, if applicable.)**

☐ The appropriate accrediting body (the ACGME, AOA or ABMS) has approved the hospital's expansion of the number of FTE residents in the program. **(The hospital must attach documentation.)**

☐ The American Osteopathic Association Residency Match Program has accepted or will be accepting the hospital's participation in the match for the existing program that will include additional resident slots in that residency training program. **(The hospital must attach documentation.)**

☐ The hospital has submitted an institutional review document or program information form for the expansion of the existing residency training program by December 1, 2010. **(The hospital must attach documentation).**

☐ (2) Hospital will likely fill the slots of the expanded residency program. (**Check at least one of the following, if applicable.)**

☐ The hospital does not have sufficient room under its FTE cap, and the hospital has other previously established residency programs, with a resident fill rate of at least 85 percent in each of program years 2007 through 2009.) **(The hospital must attach documentation.)**

☐ The hospital does not have sufficient room under its FTE cap, and the hospital is expanding an existing program in a particular specialty with a resident fill rate either nationally, within the State, or within the CBSA in which the hospital is located, of at least 85 percent. **(The hospital must attach documentation.)**

☐ A3: Demonstrated Likelihood Criterion 3. Hospital is applying for an increase in its FTE resident cap because the hospital is already training residents in an existing residency training program(s) in excess of its direct GME FTE cap or IME FTE cap, or both. **(Copies of EACH of the following must be attached.)**

● Copies of the Medicare cost reports that have been most recently submitted to the Medicare contractor by July 1, 2010 documenting on Worksheet E, Part A, Worksheet E-3, Part VI, and Worksheet E-3, Part VI the resident counts and FTE resident caps for both direct GME and IME for the relevant cost reporting periods.

● Copies of the 2010 residency match information concerning the number of residents at the hospital in its existing programs.

● Copies of the most recent accreditation letters on all of the hospital's training programs in which the hospital trains and counts FTE residents for direct GME and IME.

Section B. Level Priority Category

(Place an "X" in the appropriate box that is applicable to the level priority category that describes the applicant hospital.)

€ First Level Priority Category: The hospital is in a State whose resident-to-population ratio is within the lowest quartile, AND the hospital is in a State whose Primary Care HPSA to population ratio is in the top 10 States, AND the hospital is located in a rural area.

€ Second Level Priority Category: The hospital is in a State whose resident-to-population ratio is within the lowest quartile, AND is either in a State whose Primary Care HPSA to population ratio is in the top 10 States, or it is located in a rural area, or is an urban hospital and has or will have as of July 1, 2010, a rural training track.

€ Third Level Priority Category: The hospital is in a State whose resident-to-population ratio is within the lowest quartile.

€ Fourth Level Priority Category: The hospital is in a State whose Primary Care HPSA to population ratio is in the top 10 States, AND either the hospital is located in a rural area or the hospital is an urban hospital and has, or will have as of July 1, 2010, a rural training track.

€ Fifth Level Priority Category: The hospital is in a State whose Primary Care HPSA to population ratio is in the top 10 States, or the hospital is located in a rural area.

Section C. Evaluation Criteria

(Place an "X" in the box for each criterion that is appropriate for the applicant hospital and for the program for which the increase in the FTE cap is requested.)

€ Evaluation Criterion One. *The hospital that is requesting the increase in its FTE resident cap(s) has a Medicare inpatient utilization over 60 percent, as reflected in at least two of the hospital's last three most recent audited cost reporting periods for which there is a settled cost report.* 5 POINTS.

€ Evaluation Criterion Two. *The hospital will use the additional slots to establish a new geriatrics residency program, or to add residents to an existing geriatrics program.* 5 POINTS.

€ Evaluation Criterion Three. *The hospital will use additional slots to establish a new or expand an existing primary care program with a demonstrated focus on training residents to pursue careers in primary care, rather than in non-primary subspecialties of those primary care programs (for example, the hospital has an internal medicine program with a designated primary care track).* 3 POINTS.

€ Evaluation Criterion Four. *The hospital will use all the additional slots to establish a new or expand an existing primary care residency program or general surgery program.* – 5 POINTS.

€ Evaluation Criterion Five. *The hospital is located in a Primary Care HPSA.* 2 POINTS.

€ Evaluation Criterion Six. *The hospital is in a rural area (as defined under section 1886(d)(2)(D)(ii) of the Act) and is or will be on or after July 1, 2011, a training site for a rural track residency program (as specified under §413.79(k)), but is unable to count all of the FTE residents training in the rural track because the rural hospital's FTE cap is lower than its unweighted count of allopathic or osteopathic FTE residents as of portions of cost reporting periods on or after July 1, 2011.* 1 POINT.

Application Process and CMS Central Office and Regional Office Mailing Addresses for Receiving Increases in FTE Resident Caps

In order for hospitals to be considered for increases in their FTE resident caps, each qualifying hospital must submit a timely application. The following information must be submitted on applications to receive an increase in FTE resident caps:

- The name and Medicare provider number of the hospital.
- The name of the Medicare contractor to which the hospital submits its Medicare cost report.
- The total number of requested FTE resident slots for direct GME or IME, or both, up to 75 direct GME FTE and 75 IME FTE per hospital.
- A completed copy of the CMS Evaluation Form for each residency program for which the hospital intends to use the requested increase in FTE residents.
- Source documentation to support the assertions made by the hospital on the CMS Evaluation Form.
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report. (Include copies of Worksheets E, Part A, E-3, Part IV, and if a hospital received an increase to its FTE cap(s) under section 422 of the MMA, a copy of E-3, Part VI).
- As part of its application, we are proposing that the hospital must include the documentation that it used to arrive at its direct GME and IME primary care FTE counts, including a copy of Worksheet E-3, Part IV for direct GME, and if the hospital has an OB/GYN program, the rotation schedules corresponding to the 3 most recent cost

reporting periods ending prior to March 23, 2010 for OB/GYN, and the rotation schedules for all primary care residency programs used to establish the IME primary care FTE count corresponding to the 3 most recent cost reporting periods ending prior to March 23, 2010.

- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following information:

"I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents."

The completed application and supporting documentation (as described above) must be submitted to the CMS Central Office and the CMS Regional Office for the region in which the applicant hospital is located. The application must be received on or before December 1, 2010. The addresses of the CMS central office and regional offices are listed below.

CMS Central and CMS Regional Office Mailing Addresses for Applications for Increases in FTE Resident Caps:

Central Office

Centers for Medicare and Medicaid Services (CMS)
Director, Division of Acute Care
7500 Security Boulevard
Mail Stop C4-08-06
Baltimore, Maryland 21244
(410) 786-4548

Region I (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Financial Management and Fee for Service Operations
Region I
JFK Federal Building
Room 23275
Boston, MA 02203
Phone: (617) 565-1331

Region II (New York, New Jersey, U.S. Virgin Islands, and Puerto Rico):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations
Region II
26 Federal Plaza, 38th Floor
New York, NY 10278
Phone: (212) 616-2545

Region III (Delaware, Maryland, Pennsylvania, Virginia and West Virginia, and the District of Columbia):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations

Region III
Public Ledger Building, Suite 216

150 South Independence Mall West
Philadelphia, PA 19106
Phone: (215) 861-4140

Region IV (Alabama, North Carolina, South Carolina, Florida, Georgia, Kentucky, Mississippi, and Tennessee):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations

Region IV
Atlanta Federal Center
61 Forsyth Street, S.W., Suite 4T20
Atlanta, GA 30303-8909
Phone: (404) 562-7300

Region V (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations

Region V
233 North Michigan Avenue, Suite 600
Chicago, IL 60601
Phone: (312) 886-6432

Region VI (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations

Region VI
1301 Young Street, Suite 714
Dallas, TX 75202
Phone: (214) 767-6423

Region VII (Iowa, Kansas, Missouri, and Nebraska):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations

Region VII
Richard Bolling Federal Building
Room 235
601 East 12th Street
Kansas City, MO 64106
(816) 564-1843

Region VIII (Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations

Region VIII
Colorado State Bank Building
1600 Broadway, Suite 700
Denver, CO 80202
Phone: (303) 844-2111

Region IX (Arizona, California, Hawaii, and Nevada and Territories of American Samoa, Guam and the Commonwealth of the Northern Mariana Islands):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations

Region IX
90 7th Street, Suite 5-300 (SW)
San Francisco, CA 94103-6708
Phone: (415) 744-3501

Region X (Alaska, Idaho, Oregon, and Washington):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Medicare Financial Management
Region X
2201 Sixth Avenue, MS/RX-46
Seattle, WA 98121
Phone: (206) 615-2094

E. Preservation of Resident Cap Positions from Closed Hospitals (Section 5506 of the Affordable Care Act) (§412.105(f)(1)(ix)(B) and §413.79(o)(2))

1. Background

As we explain in Section XVII.A. of this proposed rule, Medicare makes both direct GME and IME payments to hospitals that train residents in approved medical residency training programs. Direct GME payments are made in accordance with section 1886(h) of the Act, based generally on hospital-specific PRAs, the number of FTE residents a hospital trains, and the hospital's Medicare patient share. IME payments are made in accordance with section 1886(d)(5)(B) of the Act, based generally on the ratio of the hospital's FTE residents to the number of hospital beds. Accordingly, the calculation of both direct GME and IME payments is affected by the number of FTE residents that a hospital is allowed to count; generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress instituted a cap on the number of allopathic and osteopathic residents a hospital is allowed to count for direct GME and IME purposes under the provisions of section 1886(h)(4)(F) of the Act for direct GME and section 1886(d)(5)(B)(v) of the Act for IME. Dental and podiatric residents were not included in this statutorily mandated cap. For most hospitals, the limit, or cap, is the unweighted number of allopathic and osteopathic FTE residents training in the hospital's most recent cost reporting period ending on or before December 31, 1996. Thus, each teaching hospital FTE resident cap is unique to the number of FTE residents that it

trained in the hospital's most recent cost reporting period ending on or before December 31, 1996.

Under existing regulations at §413.79(h) for direct GME and §412.105(f)(1)(ix) for IME, a hospital that is training FTE residents at or in excess of its FTE resident caps and takes in residents displaced by the closure of another teaching hospital may receive a temporary increase to its FTE residents caps so that it may receive direct GME and IME payment associated with those displaced FTE residents. However, those temporary FTE resident cap increases are associated with those specific displaced FTE residents, and the increases expire as those displaced residents complete their training program. Thus, if a teaching hospital closes, its direct GME and IME FTE resident cap slots would be "lost," because those cap slots are associated with a specific hospital's Medicare provider agreement, which would be retired upon the hospital's closure. The closure of a teaching hospital, particularly if it is a large academic medical center, could mean not only the displacement of hundreds of residents, but also the permanent loss of hundreds of Medicare-funded residency training slots and a sophisticated GME infrastructure that could take many years to rebuild, threatening the availability of health care services in a community. Section 5506 of the Affordable Care Act addresses this situation by amending section 1886(h)(4)(H) of the Act to add a new clause (vi) that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria by the number of FTE resident positions in the closed hospital's training programs.

Section 5506 of the Affordable Care Act specifically instructs the Secretary to increase the FTE resident caps for other hospitals based upon the FTE resident positions in teaching hospitals that closed "on or after a date that is 2 years before the date of enactment" (that is, March 23, 2008). Although certain of the FTE cap increases granted pursuant to section 5506 will be based on hospital closures that occurred prior to this notice and comment rulemaking procedure, the process we are proposing to establish in the CY 2011 OPPS Final Rule would also be used for all future teaching hospital closures. We are in the process of instructing the Medicare contractors to notify us of every teaching hospital that has closed since March 23, 2008, and of the direct GME and IME FTE caps for each of those closed hospitals. We plan to use this information to determine how many slots are currently available for increases to other hospitals' FTE resident caps.

We note that section 1886(h)(4)(H)(vi)(IV) of the Act, as added by section 5506(a) of the Affordable Care Act, states that "The aggregate number of increases in the otherwise applicable resident limits for the hospitals under this clause shall be equal to the number of resident positions in the approved medical residency programs that closed on or after" March 23, 2008. For purposes of implementing this section 1886(h)(4)(H)(vi)(IV), we are proposing to interpret "the number of resident positions" to mean the number that is equal to the IME and direct GME FTE resident caps of a hospital that closed, or will close. We do not believe the intent of this provision is to distribute and pay for more FTE resident slots than the amount equal to a closed hospital's IME and direct GME FTE resident caps, in the instance where a closed hospital was training more

FTE residents than its FTE resident caps. Further, in the situation where a closed hospital was training FTE residents below its caps, we believe that for the sake of ensuring that a community could retain up to its full training strength, we believe it is appropriate to distribute, not the actual number of slots the closed hospital had been training prior to its closure, but the number of FTE resident slots equal to the IME and direct GME FTE caps of the closed hospital.

2. Definition of a "Closed Hospital"

Section 1886(h)(4)(H)(vi) of the Act, as added by section 5506(a) of the Affordable Care Act, states that "the Secretary shall, by regulation, establish a process under which, in the case where a hospital (other than a hospital described in clause (v)) with an approved medical residency program *closes* on or after" March 23, 2008, the Secretary shall increase the FTE resident caps of other hospitals accordingly (emphasis added). Under existing regulations at §489.52 and §413.79(h), "closure of a hospital" means the hospital terminates its Medicare provider agreement. We are proposing to define a "closed teaching hospital" for purposes of section 5506 in a similar manner, but would also specify that the FTE resident cap slots of the hospital that closed no longer exist as part of any other hospital's permanent FTE resident cap. Thus, we are proposing that this provision would not apply to hospitals that declare bankruptcy but are still participating under the same Medicare provider agreement, nor would it apply to teaching hospitals that remain open, but close one or more residency programs. It also would not apply to mergers, because in the case of a merger, the Medicare provider agreement of

one hospital is subsumed into the provider agreement of the surviving provider; no provider agreement is retired, even if operations at one facility are scaled back or ceased.

However, we are proposing that the proposed revised definition of hospital closure for purposes of implementing section 5506 *would* apply in the case of acquisitions, where the new owner *retires* the Medicare provider agreement of the hospital it purchased, thus abdicating the FTE resident cap slots associated with that provider agreement, even if the new owner will continue to operate the hospital exactly as it had been operated before the acquisition (that is, makes no changes to the bed size, infrastructure, services, and GME programs). We believe this is appropriate because section 5506 of the Affordable Care Act specifically addresses hospital "closure" and ensures preservation of the FTE cap slots within a community when a teaching hospital does "close," based on specified criteria for redistributing the slots from the closed hospital to increase the FTE caps for other hospitals. However, as we explain further below, it is possible for the new hospital formed in an acquisition to receive preference in receiving an increase to its FTE resident caps based on redistributed slots from the closed hospital that it acquired.

Section 1886(h)(4)(H)(vi) of the Act, as added by section 5506(a), also states that "the Secretary shall, by regulation, establish a process under which, in the case where a hospital *(other than a hospital described in clause (v))* with an approved medical residency program closes . . ." (emphasis added). A hospital described in section 1886(h)(4)(H)(v) of the Act is an entity that enters into a provider agreement pursuant to section 1866(a) of the Act to provide hospital services on the same physical site

previously used by Medicare Provider No. 05-0578. Accordingly, we are proposing not to redistribute any FTE cap slots associated with Medicare Provider Number 05-0578.

3. Priority for Hospitals in Certain Areas

Section 1886(h)(4)(H)(vi)(II), as added by section 5506(a) of the Affordable Care Act, specifies that the Secretary shall distribute the FTE cap increases in the following priority order, "with preference given within each category to hospitals that are members of the same affiliated group" (as defined by the Secretary) as the closed hospital:

- First, to hospitals located in the same core-based statistical area (CBSA) as, or in a CBSA contiguous to, the hospital that closed.
- Second, to hospitals located in the same State as the closed hospital.
- Third, to hospitals located in the same region as the hospital that closed.
- Fourth, if the slots have not yet been fully distributed, to qualifying hospitals in accordance with the criteria established under section 5503 ("Distribution of Additional Residency Positions") of the Affordable Care Act.

First, we are proposing to use the same pre-reclassification CBSAs that are used for wage index purposes under the IPPS in determining which hospitals are located in the same or contiguous CBSAs as the CBSA in which the hospital that closed was located, without regard to any reclassifications made under the provisions of §§412.102, 412.103, 412.230, 412.232, 412.234, and 412.235 of the regulations. Second, we are proposing to define "State" in the second priority category to include Puerto Rico and the District of Columbia. Third, we are proposing to define "region" in the third priority category as Census Region, consistent with the use of the term elsewhere in the GME regulations.

(The term is used for purposes of establishing direct GME PRAs of certain new teaching hospitals at §413.77(e)(1)(iii).) Fourth, as specified in the fourth priority category, we are proposing to employ the criteria for redistribution of residency positions described in section 5503 of the Affordable Care Act, as implemented in the proposed revised regulations at §413.79(n), should there be any slots not redistributed under the first through third priority categories.

With regard to members of the same Medicare GME affiliated group, we are proposing to give priority within each category to hospitals that are members of the same Medicare GME affiliated group as the hospital that closed. A Medicare GME affiliated group, as defined at §413.75(b), consists of hospitals that enter into a Medicare GME affiliation agreement, also as defined at §413.75(b), for the purpose of cross-training residents and that, under the terms of the agreement, aggregate and make temporary adjustments to their respective individual FTE resident caps. To provide flexibility to hospitals that have affiliated with the hospital that closed, we are proposing to refer to the most recent Medicare GME affiliation agreement of which the closed hospital was a member. Hospitals that were listed as participants of the Medicare GME affiliated group on that most recent affiliation agreement before the closure of the hospital will receive preference in receiving FTE cap increases based on the redistributed slots.

4. Application Process

We are proposing to establish an application process for hospitals to apply to CMS to receive an increase in FTE caps based on slots from closed hospitals. Section 5506 of the Affordable Care Act did not specify an effective date or an application

deadline for hospitals to request an increase to their caps when a hospital closes. Accordingly, with respect to the first application process to be implemented for section 1886(h)(4)(H)(vi) of the Act, as added by section 5506(a) of the Affordable Care Act, and which includes all teaching hospital closures back to March 23, 2008, we are proposing that the application deadline would be January 1, 2011. For future teaching hospital closures, we are proposing that we would inform the public through an appropriate medium that increases to hospitals' FTE resident caps are available for redistribution due to the closure of a teaching hospital, and the application deadline would be 4 months following the issuance of that notice to the public.

5. Ranking Criteria

Unlike the application process for FTE cap increases under section 1886(h)(8) of the Act as added by section 5503 of the Affordable Care Act, we are not proposing to establish a "point" system to distinguish between hospitals within each of the first three priority categories. Rather, within each of the three first statutory priority categories in section XVII.E.3. of this proposed rule (that is, same or contiguous CBSAs, same State, and same Region), we are proposing to rank categories in which we would assign slots first to hospitals that fall within the first ranking category before assigning slots to those hospitals that fall within the second ranking category, and would assign slots to those hospitals that fall within the second ranking category before assigning slots to hospitals in the third ranking category, and so forth. We are not proposing to use these ranking categories within the fourth priority category because, under that fourth priority category, the Secretary would use the process established under section 5503 for section 1886(h)(8)

of the Act. In order to maintain stability in existing GME programs, these proposed ranking categories generally give preference to applying hospitals that demonstrate a commitment to continue training residents in the same programs that the closed hospital operated, or that had a training relationship with the closed hospital (such as a Medicare GME affiliation agreement).

- Ranking Criterion One. *The applying hospital is requesting the increase in its FTE resident cap(s) because it is assuming (or assumed) an entire program (or programs) from the hospital that closed, and the applying hospital is continuing to operate the program(s) exactly as it had been operated by the hospital that closed (that is, same residents, same program director, and same (or many of the same) teaching staff).* We are proposing this ranking criterion because we understand that there are situations where, when a hospital is acquired and its provider agreement is retired and a new provider agreement is established in the place of the old one, the new formed "acquiring" hospital continues to operate the GME programs seamlessly and in the same manner as under the previous provider agreement. If this situation occurs, we believe the new hospital with the new provider agreement is demonstrating a strong commitment to not only maintain the GME programs in the community for the long term (that is, continuity), but to also allow the residents that were at the hospital when the change in provider agreement occurred to continue to train there, such that no residents are displaced and no training is interrupted.

Alternatively, it is possible that perhaps a year or more prior to a hospital's closure, the hospital closed some or all of its residency programs, and another hospital

assumed an entire program (or programs) at the time of the residency program's closure, and the applying hospital has continued to operate that program seamlessly, as it had been operated at the hospital that ultimately closed. Since the applying hospital has also demonstrated a strong commitment to continuity of the residency program(s) in the community by assuming the program(s) even prior to the other hospital's closure, we are proposing that the applying hospital would be categorized in Ranking Criterion One.

- Ranking Criterion Two. *The applying hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the applying hospital received slots from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement.* We are proposing this ranking criterion because section 1886(h)(4)(H)(vi) of the Act, as added by section 5506(a) of the Affordable Care Act, directs the Secretary to give preference to hospitals that are members of the same affiliated group as the hospital that closed. We believe that, generally, if the applying hospital was affiliated to receive slots from the hospital that closed, then the applying hospital was relying on that number of FTE resident slots that it received in order to maintain its fair share of the cross-training of the residents in the jointly operated programs. In the absence of those slots received from the closed hospital, the applying hospital may not be able to continue training that number of FTE residents, and those same residents would not only be displaced from the closed hospital,

but might essentially become “displaced” from the affiliated hospitals in which they were used to doing a portion of their training. Accordingly, we are proposing this ranking criterion to allow hospitals that were affiliated with the closed hospitals to at least maintain their fair share of the training of the residents in the programs that they had jointly operated with the closed hospital. We note that we are proposing this ranking criterion regarding affiliated hospitals as second, after the first ranking criterion regarding applying hospitals that assume an entire program or programs from the closed hospital because, even though section 5506 of the Affordable Care Act directs the Secretary to give preference to members of the same affiliated group, we believe that a hospital that assumes the responsibility for an entire program or programs demonstrates a commitment to maintain the programs to an even greater degree than does a hospital that was affiliated with the hospital that closed and may only be maintaining a portion of the residency program or programs.

- Ranking Criterion Three. *The applying hospital took in residents displaced by the closure of the hospital, but is not assuming an entire program or programs, and will use the additional slots to continue training residents in the same programs as the displaced residents, even after those displaced residents complete their training (that is, the applying hospital is permanently expanding its own existing programs).* Similar to Ranking Criterion Two, hospitals fitting into Ranking Criterion Three also demonstrate a commitment to protect residents displaced by a hospital’s closure, and to ensure that there is a degree of continuity in the community with respect to the particular training program or programs that the closed hospital operated. However, because an applying hospital

fitting into this category was not part of the same Medicare GME affiliated group as the closed hospital, we are proposing that this category would be ranked as third, below Ranking Criterion Two which relates to hospitals that were members of the same affiliated group as the closed hospital.

The next five proposed ranking criteria would apply in the instance where there are still slots available from the closed hospital after distributing slots to hospitals falling within the first three ranking criteria. Thus, hospitals fitting into Ranking Criteria Four through Eight would not fit into Ranking Criteria One, Two, or Three, but they can demonstrate that they will use the slots in a manner that is consistent with current Medicare policy goals, as indicated in section 5503 of the Affordable Care Act, such as using the slots for a geriatrics or for other primary care residency programs, or for a general surgery residency program.

- Ranking Criterion Four. *The applying hospital does not fit into Ranking Criteria One, Two, or Three, and will use additional slots to establish a new or expand an existing geriatrics residency program.*

- Ranking Criterion Five. *The applying hospital does not fit into Ranking Criteria One, Two, or Three, is located in a Primary Care HPSA, and will use all the additional slots to establish a new or expand an existing primary care residency program*.

- Ranking Criterion Six.- *The applying hospital does not fit into Ranking Criteria One, Two, or Three, and will use all the additional slots to establish a new or expand an existing primary care residency program.*

- Ranking Criterion Seven.- *The applying hospital does not fit into Ranking Criteria One, Two, or Three, and will use all the additional slots to establish a new or expand an existing general surgery residency program*.

- Ranking Criterion Eight.- *The applying hospital does not fit into Ranking Criteria One through Seven.*

6. Demonstrated Likelihood of Filling the Positions within a Certain Time Period

Section 1886(h)(4)(H)(vi) of the Act, as added by section 5506(a) of the Affordable Care Act, does not place a limit on the number of slots an applying hospital may request, although under section 1886(h)(4)(H)(iv)(IV) of the Act, the Secretary must ensure that the aggregate number of increases to hospitals' FTE residents caps are equal to the FTE residents caps of the hospital that closed. However, section 1886(h)(4)(H)(iv)(III) of the Act specifies that the Secretary may only award slots to an applying hospital "if the Secretary determines that the hospital has demonstrated a likelihood of filling the positions made available under this clause within 3 years." We are proposing that hospitals must provide documentation to demonstrate the likelihood of filling requested slots under section 5506 within 3 years. For example, the applying hospital would document that it does not have sufficient room under its FTE resident caps to take in the additional residents, and has approval from the relevant accrediting body to take over the closed hospital's residency program(s), or expand its own residency program(s) to reflect a permanent commitment to train additional residents. We are proposing that "within 3 years" would mean within the 3 academic years immediately following the application deadline to receive slots after a particular hospital closes. For

example, where the application deadline is January 1, 2011, the immediately following academic year is July 1, 2011, and therefore, hospitals must demonstrate the likelihood of filling their slots by June 30, 2014.

7. No Duplication of FTE Cap Slots

Section 5506(d) of the Affordable Care Act specifies that "the Secretary shall give consideration to the effect of the amendments made by this section on any temporary adjustment to a hospital's FTE cap under §413.79(h) . . . (as in effect on the date of enactment of this Act) in order to ensure that there is no duplication of FTE slots . . ." Under existing regulations at §413.79(h), hospitals that take in residents that are displaced by the closure of another hospital may receive temporary increases to their FTE resident caps so that they may receive payment for training the specific displaced residents. The temporary cap adjustment lasts only for the duration of a specific displaced resident's training. In distributing slots permanently under section 5506, we may need to be cognizant of the number of FTE residents for whom a temporary FTE cap adjustment was provided, and when those residents will complete their training, at which point the temporary slot associated with those displaced residents would be available for permanent redistribution.

We believe that it will only be necessary to delay permanent assignment of FTE cap slots in instances where if, after fulfilling the requests of hospitals that qualify to receive additional slots under Ranking Criteria One, Two, and Three, there are still excess slots available. In the case where an applying hospital fits within Ranking Criterion One, we are proposing to revise the existing regulations at §413.79(h) limiting

temporary cap adjustments for displaced residents *by the number of FTE residents in the program(s) in which the applying hospital is operating seamlessly.* We are proposing to immediately assign permanently that number of FTE slots to the qualifying hospital. For example, if teaching hospital B assumes an entire internal medicine program with 20 FTEs from closed hospital A, no temporary FTE cap adjustment under §413.79(h) would be needed for those internal medicine residents, and teaching hospital B would immediately receive a permanent FTE resident cap increase of 10 FTE residents. Similarly, in the case where an applying hospital fits within Ranking Criterion Two, we are proposing to revise the existing regulations at §413.79(h) limiting temporary cap adjustments for displaced residents *by the number of FTE residents that the applying hospital received under the terms of the affiliation agreement from the closed hospital.* We are proposing to immediately assign permanently that number of FTE slots to the qualifying hospital. For example, if teaching hospital D had received 30 FTE slots from closed hospital C under the terms of a Medicare GME affiliation agreement for the purposes of a shared rotational arrangement (as defined at §413.75(b)) for a general surgery program, teaching hospital D would immediately receive a permanent FTE resident cap increase of 30 FTE residents, which would enable hospital D to continue to receive direct GME and IME payment for its share of training 30 general surgery residents.

Lastly, in the case where an applying hospital fits within Ranking Criterion Three, we are proposing to revise §413.79(h) to provide for temporary cap adjustments for displaced residents *by the number of displaced FTE residents the applying hospital takes*

in, and to immediately assign permanently that number of FTE slots to the qualifying hospital. For example, if Hospital E takes in three FTE displaced residents in a family medicine program, and not only trains those three displaced residents until they complete their training, but permanently expands its existing family medicine program such that it will add three more FTEs in the place of three that completed their training, we would immediately assign three FTEs permanently to Hospital E, bypassing any temporary adjustment under §413.79(h). Accordingly, there would be no duplication of FTE slots when distributing slots to hospitals that qualify under the first three ranking criteria.

If, after distributing the slots from a closed hospital to increase the FTE caps for applying hospitals that fall within Ranking Criteria One, Two, and Three, there are still excess slots available, it is possible that those excess slots might be associated with displaced residents for whom temporary cap adjustments under §413.79(h) <u>are</u> necessary. That is, it is possible that in the case where applying hospitals do not permanently assume *all* of the closed hospital's residents and programs, temporary cap transfers under §413.79(h) would be necessary to allow the remaining residents to complete their training. Therefore, we are proposing to distribute the slots accordingly to increase the FTE resident caps for hospitals that fall within Ranking Criteria Four through Seven. However, to avoid duplicate FTE counting, we would only permanently assign the slots to the qualified hospitals falling within Ranking Criteria Four through Seven once the displaced residents have completed their training and their temporary cap adjustments have expired.

We are proposing to add new regulations text at §412.105(f)(1)(ix)(B) for IME and §413.79(o)(2)) for direct GME to reflect the provisions of section 5506 of the Affordable Care Act. In addition, we have proposed some very minor changes to direct GME and IME existing text in order to clarify meaning and standardize the terminology that is used throughout.

8. Other Payment Issues Regarding Hospitals that Receive Increase in FTE Caps Based on Slots from Closed Hospitals

We note that section 1886(h)(4)(H)(vi) of the Act, as added by the Affordable Care Act, makes no reference to section 1886(h)(4)(G) or 1886(d)(5)(B)(vi)(II) of the Act, which are the provisions concerning the rolling average count of FTE residents. Furthermore, there is no mention of section 1886(d)(5)(B)(vi)(I) of the Act, the provision regarding the cap on the IME resident-to-bed ratio, in section 1886(h)(4)(H)(vi) either. That is, the statute does not provide for an exclusion from application of the rolling average for residents counted as a result of FTE cap increases under section 1886(h)(4)(H)(vi) of the Act, nor does the statute exempt these residents from the application of the cap on the IME resident-to-bed ratio. In light of the absence of a specific directive in section 1886(h)(4)(H)(vi) of the Act exempting those residents from application of the rolling average for direct GME and IME, and the cap on the IME resident-to-bed ratio, and with no apparent reason to treat residents counted as a result of the FTE cap increases under section (h)(4)(H)(vi) of the Act differently, we are proposing to require that if a hospital increases its direct GME or IME FTE count of residents as a result of an FTE resident cap increase under section 1886(h)(4)(H)(vi) of the Act, those

FTE residents would be immediately subject to the rolling average calculation and the cap on the IME resident-to-bed ratio.

We also note that section 1886(h)(4)(H)(vi) of the Act for direct GME and section 1886(d)(5)(B)(v) of the Act for IME does not specify use of a special direct GME PRA or IME multiplier for residents counted by a hospital under an FTE cap increase received after the closure of another hospital. Therefore, we are proposing that residents counted by a hospital under a permanent adjustment to the hospital's FTE resident caps under the provisions of section 5506 of the Affordable Care Act would be paid for using the receiving hospital's otherwise applicable direct GME PRA (which is hospital-specific) and IME multiplier (which is the same for all hospitals). Further, as we have proposed with respect to FTE resident cap increases awarded under section 5503 (section XVII.D. of this proposed rule), we are proposing that these slots may not be used as part of the aggregate FTE resident cap under a Medicare GME affiliation agreement. We believe this prohibition is appropriate given that the receiving hospital has demonstrated that it needs the additional slots, and therefore, those slots should remain at the receiving hospital.

9. Application--No Reopening of Settled Cost Reports

Section 5506(c) of the Affordable Care Act specifies that the changes made by the provisions of sections 5506(a) and (b) should not be applied in a manner that would require the reopening of settled cost reports for which there is not a pending, jurisdictionally proper appeal on direct GME or IME payments as of March 23, 2010 (the date of the enactment of Pub. L. 111-148). Such language would typically be appropriate

for a provision with a retroactive effective date (such as section 5505), and since section 5506 does not have a retroactive effective date, we are unsure of the purpose of this language in section 5506. Nevertheless, we are proposing to reflect this provision in the proposed revisions under §412.105(f)(1)(ix)(B), and §413.79(o)(2)(ii) of the regulations. In addition, as we explained previously regarding sections 5504 and 5505, we are proposing to interpret "pending, jurisdictionally proper appeal on direct GME or IME payments" to mean that in order for a hospital to request a change to its FTE count, direct GME or IME respectively, the "pending, jurisdictionally proper appeal" must be specific to direct GME or IME respectively. For example, in order for a hospital to increase its FTE count with regard to an Affordable Care Act provision that is unique to IME (such as inclusion in the IME count of didactic time occurring in the hospital as specified by new section 1886(d)(5)(B)(x)(II)), the hospital's "pending, jurisdictionally proper appeal" must be on an IME issue; IME FTEs or the available bed count. However, if the hospital's "pending, jurisdictionally proper appeal" is on an issue that only affects direct GME payments, such as the initial residency period or the Medicare patient load, that appeal would not be sufficient in order for the hospital to increase its FTE count with regard to an Affordable Care Act provision that is unique to IME, such as didactic time in the hospital setting.

CMS Evaluation Form
As Part of the Application for the Increase in a Hospital's FTE Cap(s) Under Section 5506 of the Affordable Care Act: Preservation of FTE Cap Slots from Teaching Hospitals that Close

Directions: Please fill out the information below for each residency program for which the applicant hospital intends to use the increase in its FTE cap(s). The applicant hospital is responsible for complying with the other requirements listed in the CY 2011 Hospital Outpatient Prospective Payment System rule in order to complete its application for the increase in its FTE cap(s) under section 5506 of Public Law 111-148.

NAME OF HOSPITAL: _____

MEDICARE PROVIDER NUMBER: _____

NAME OF MEDICARE CONTRACTOR: _____

NAME OF SPECIALTY TRAINING PROGRAM: _____

(Check one): □ Allopathic Program □ Osteopathic Program

NUMBER OF FTE SLOTS REQUESTED FOR PROGRAM:

Direct GME: _____ IME: _____

Section A: Demonstrated Likelihood of Filling the FTE Slots

Demonstrated Likelihood: Hospital must provide documentation to demonstrate the likelihood of filling requested slots under section 5506 within 3 years. For example, the applying hospital would document that it does not have sufficient room under its FTE resident caps to take in the additional residents, and has approval from the relevant accrediting body to take over the closed hospital's residency program(s), or expand its own residency program(s) to reflect a permanent commitment to train additional residents.

(1) Hospital will establish this newly approved residency program or will expand an existing residency program. **(The hospital must check at least one of the following, if applicable.)**

☐ Application for approval of the new residency program has been submitted to the ACGME, AOA or the ABMS. **(The hospital must attach a copy.)**

☐ The hospital has submitted an institutional review document or program information form concerning the new program in an application for approval of the new program. **(The hospital must attach a copy.)**

☐ The hospital has received written correspondence from the ACGME, AOA or ABMS acknowledging receipt of the application for the new or expanded program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit). **(The hospital must attach a copy.)**

(2) Hospital does not have sufficient room under its direct GME FTE cap or IME FTE cap, or both, and has or is seeking approval from the relevant accrediting body to take over the closed hospital's residency program(s), or expand its own residency program(s) to reflect a permanent commitment to train additional residents. (**The hospital must check at least one of the following, if applicable.)**

☐ Application for approval of the residency program has been submitted to the ACGME, AOA or the ABMS. **(The hospital must attach a copy.)**

☐ The hospital has submitted an institutional review document or program information form concerning the program in an application for approval of the program. **(The hospital must attach a copy.)**

☐ The hospital has received written correspondence from the ACGME, AOA or ABMS acknowledging receipt of the application for the program, or other types of communication from the accrediting bodies concerning the program approval process (such as notification of site visit). **(The hospital must attach a copy.)**

(3) Hospital will likely fill the slots requested. **(The hospital must check the following, if applicable.)**

☐ The hospital does not have sufficient room under its direct GME FTE cap or IME FTE cap, or both. **(Copies of EACH of the following must be attached.)**

● Copies of the Medicare cost reports that have been most recently submitted to the Medicare contractor documenting on Worksheet E, Part A, Worksheet E-3, Part VI, and Worksheet E-3, Part VI the resident counts and FTE resident caps for both direct GME and IME for the relevant cost reporting periods.

● Copies of the most recent residency match information concerning the number of residents at the hospital in its existing programs.

● Copies of the most recent accreditation letters on all of the hospital's training programs in which the hospital trains and counts FTE residents for direct GME and IME.

(4) Applying hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the applying hospital received slots from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement. **(Copies of EACH of the following must be attached.)**

● Copies of the most recent Medicare GME affiliation agreement of which the applying hospital and the closed hospital were a member of before the hospital closed.

● Copies of the Medicare cost reports that have been most recently submitted to the Medicare contractor documenting on Worksheet E, Part A, Worksheet E-3, Part VI, and Worksheet E-3, Part VI the resident counts and FTE resident caps for both direct GME and IME for the relevant cost reporting periods.

● Copies of the most recent accreditation letters for all of the hospital's training programs in which the hospital had a shared rotational arrangement (as defined at §413.75(b)) with the closed hospital.

Section B. Level Priority Category

(Place an "X" in the appropriate box that is applicable to the level priority category that describes the applicant hospital.)

a) □ First, to hospitals located in the same core-based statistical area (CBSA) as, or in a CBSA contiguous to, the hospital that closed.

b) □ Second, to hospitals located in the same State as the closed hospital.

c) □ Third, to hospitals located in the same region as the hospital that closed.

d) □ Fourth, if the slots have not yet been fully distributed, to qualifying hospitals in accordance with the criteria established under section 5503, "Distribution of Additional Residency Positions"

Section C. Evaluation Criteria

(Place an "X" in the box for each criterion that is appropriate for the applicant hospital and for the program for which the increase in the FTE cap is requested.)

☐ Ranking Criterion One. *The applying hospital is requesting the increase in its FTE resident cap(s) because it is assuming (or assumed) an entire program (or programs) from the hospital that closed, and the applying hospital is continuing to operate the program(s) exactly as it had been operated by the hospital that closed (that is, same residents, same program director, same (or many of the same) teaching staff)*

☐ Ranking Criterion Two. *The applying hospital was listed as a participant of a Medicare GME affiliated group on the most recent Medicare GME affiliation agreement of which the closed hospital was a member before the hospital closed, and under the terms of that Medicare GME affiliation agreement, the applying hospital received slots from the hospital that closed, and the applying hospital will use the additional slots to continue to train at least the number of FTE residents it had trained under the terms of the Medicare GME affiliation agreement.*

☐ Ranking Criterion Three. *The applying hospital took in residents displaced by the closure of the hospital, but is not assuming an entire program or programs, and will*

use the additional slots to continue training residents in the same programs as the displaced residents, even after those displaced residents complete their training (that is, the applying hospital is permanently expanding its own existing programs).

☐ Ranking Criterion Four.- *The applying hospital does not fit into Ranking Criteria 1, 2, or 3, and will use additional slots to establish a new or expand an existing geriatrics residency program.*

☐ Ranking Criterion Five.- *The applying hospital does not fit into Ranking Criteria 1, 2, or 3, is located in a Primary Care HPSA, and will use all the additional slots to establish a new or expand an existing primary care residency program.*

☐ Ranking Criterion Six.- *The applying hospital does not fit into Ranking Criteria 1, 2, or 3, and will use all the additional slots to establish a new or expand an existing primary care residency program.*

☐ Ranking Criterion Seven.- *The applying hospital does not fit into Ranking Criteria 1, 2, or 3, and will use all the additional slots to establish a new or expand an existing general surgery residency program.*

☐ Ranking Criterion Eight.- *The applying hospital does not fit into Ranking Criteria 1 through 7.*

Application Process and CMS Central Office and Regional Office Mailing Addresses for Receiving Increases in FTE Resident Caps

In order for hospitals to be considered for increases in their FTE resident caps, each qualifying hospital must submit a timely application. The following information must be submitted on applications to receive an increase in FTE resident caps:

- The name and Medicare provider number, and Medicare contractor (to which the hospital submits its cost report) of the hospital.

- The total number of requested FTE resident slots for direct GME or IME, or both.

- A completed copy of the CMS Evaluation Form for each residency program for which the hospital intends to use the requested increase in FTE residents.

- Source documentation to support the assertions made by the hospital on the CMS Evaluation Form.

- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report. (Include copies of Worksheets E, Part A, E-3, Part IV, and if a hospital received an increase to its FTE cap(s) under section 422 of the MMA, a copy of E-3, Part VI).

- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following information:

"I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under federal law. Furthermore, I

understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents."

The completed application and supporting documentation (as described above) must be submitted to the CMS Central Office and the CMS Regional Office for the region in which the applicant hospital is located. The addresses of the CMS Central Office and Regional Offices are listed below.

CMS Central and CMS Regional Office Mailing Addresses for Applications for Increases in FTE Resident Caps:

Central Office

Centers for Medicare and Medicaid Services (CMS)
Director, Division of Acute Care
7500 Security Boulevard
Mail Stop C4-08-06
Baltimore, Maryland 21244
(410) 786-4548

Region I (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator, Division of Financial Management and Fee for Service Operations
Region I
JFK Federal Building

Room 23275
Boston, MA 02203
Phone: (617) 565-1331

Region II (New York, New Jersey, U.S. Virgin Islands, and Puerto Rico):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations
Region II
26 Federal Plaza, 38th Floor
New York, NY 10278
Phone: (212) 616-2545

Region III (Delaware, Maryland, Pennsylvania, Virginia and West Virginia, and the District of Columbia):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations
Region III
Public Ledger Building, Suite 216
150 South Independence Mall West
Philadelphia, PA 19106
Phone: (215) 861-4140

Region IV (Alabama, North Carolina, South Carolina, Florida, Georgia, Kentucky, Mississippi, and Tennessee):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations
Region IV
Atlanta Federal Center
61 Forsyth Street, S.W., Suite 4T20
Atlanta, GA 30303-8909
Phone: (404) 562-7300

Region V (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations
Region V

233 North Michigan Avenue, Suite 600
Chicago, IL 60601
Phone: (312) 886-6432

Region VI (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations
Region VI
1301 Young Street, Suite 714
Dallas, TX 75202
Phone: (214) 767-6423

Region VII (Iowa, Kansas, Missouri, and Nebraska):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations
Region VII
Richard Bolling Federal Building
Room 235
601 East 12th Street
Kansas City, MO 64106
(816) 564-1843

Region VIII (Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations
Region VIII
Colorado State Bank Building
1600 Broadway, Suite 700
Denver, CO 80202
Phone: (303) 844-2111

Region IX (Arizona, California, Hawaii, and Nevada and Territories of American Samoa, Guam and the Commonwealth of the Northern Mariana Islands):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations

Region IX
90 7th Street, Suite 5-300 (SW)
San Francisco, CA 94103-6708
Phone: (415) 744-3501

Region X (Alaska, Idaho, Oregon, and Washington):

Centers for Medicare and Medicaid Services (CMS)
Associate Regional Administrator,
Division of Financial Management and Fee for Service Operations
Region X
2201 Sixth Avenue, MS/RX-46
Seattle, WA 98121
Phone: (206) 615-2094

XVIII. Proposed Changes to Whole Hospital and Rural Provider Exceptions to the Physician Self-Referral Prohibition and Related Changes to Provider Agreement Regulations

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 he or she (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)(1) of the Act provides that an

ownership or investment interest in a hospital located in Puerto Rico shall not be considered to be an ownership or investment interest. 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 are 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 Relating to the Whole Hospital and Rural Provider Exceptions to Ownership and Investment Prohibition

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 to qualify for such exceptions. The statute defines a "physician owner or investor" in a hospital as a physician or an immediate family member of a physician who has a direct or indirect ownership or investment interest in the hospital. We will refer to hospitals with such "physician owners or investors" as "physician-owned hospitals."

Section 6001(a)(2) of the Affordable Care Act provides that in order to satisfy the whole hospital exception, a physician-owned hospital must meet the requirements

described in a new section 1877(i)(1) of the Act no later than September 23, 2011. Section 6001(a)(1) amended the rural provider exception to require that hospitals located in rural areas also satisfy the requirements of new section 1877(i)(1) of the Act no later than September 23, 2011.

Section 6001(a)(3) of the Affordable Care Act, as amended by the HCERA, sets forth the terms of new section 1877(i)(1) of the Act. Under section 1877(i)(1) of the Act, a hospital must:

(1) Have physician owners or investors and a provider agreement in effect no later than December 31, 2010;

(2) Not expand facility capacity beyond the number of operating rooms, procedure rooms, and beds for which the hospital was licensed as of March 23, 2010, unless an exception is granted by the Secretary;

(3) Comply with certain reporting and disclosure requirements and not condition any physician ownership or investment interests directly or indirectly on a physician making or influencing referrals to or generating other business for the hospital;

(4) Comply with certain requirements designed to ensure that all ownership and investment interests in the hospital are *bona fide*;

(5) Inform patients before admission if the hospital does not have a physician available on the premises during all hours and receive a signed acknowledgment that the patient understands this fact; and

(6) Not have been converted from an ASC on or after March 23, 2010.

In addition, section 1877(i)(2) of the Act requires the Secretary to collect, publish, and update on an annual basis on the CMS Web site (http://www.cms.hhs.gov) the physician and other ownership information submitted by hospitals under section 1877(i)(1)(C)(i) of the Act. Section 1877(i)(3) of the Act requires the Secretary to create an exception process related to the prohibition on expansion of facility capacity and publish in the **Federal Register** the final decision with respect to each applicant hospital.

Section 6001(b)(1) of the Affordable Care Act requires the Secretary to establish policies and procedures to ensure compliance with the requirements described in section 1877(i)(1) of the Act, which may include unannounced site reviews of hospitals. Section 6001(b)(2) of the Affordable Care Act requires the Secretary, beginning no later than May 1, 2012, to conduct audits to determine whether hospitals are in compliance with the requirements of new section 1877(i)(1).

As noted above, physician-owned hospitals must meet the requirements of new section 1877(i)(1) of the Act not later than 18 months after the date of enactment (that is, by September 23, 2011). We have received numerous inquiries concerning how this language relates to several of the requirements set forth in section 1877(i)(1) of the Act that specify earlier deadlines. We believe that compliance with all requirements must occur no later than September 23, 2011, and failure to satisfy earlier deadlines will preclude use of the revised exceptions after the earlier deadline has passed. For example, section 1877(i)(1)(A) of the Act provides that the hospital must have had physician ownership or investment on December 31, 2010, and a provider agreement in effect on

that date. Failure to obtain a provider agreement that is effective on or before December 31, 2010, will preclude use of the revised rural provider and whole hospital exceptions on and after January 1, 2011. Another example can be seen in section 1877(i)(1)(D)(i) of the Act, which provides that the percentage of the total value of physician ownership or investment interests held in the hospital, in the aggregate, must not exceed such percentage as of March 23, 2010. Therefore, if a hospital has no physician ownership or investment as of March 23, 2010, and later adds physician owners or investors, the hospital will not satisfy the whole hospital and rural provider exceptions. Most of the provisions within section 1877(i)(1) of the Act do not specify an explicit deadline for compliance. Thus, we are proposing that the deadline for compliance with all provisions within section 1877(i)(1) of the Act that do not contain an explicit deadline is September 23, 2011, that is, 18 months after the date of enactment.

Below, we discuss changes we are proposing to make to our regulations in response to section 6001 of the Affordable Care Act, as amended.

C. Proposed Changes to Physician Self-Referral Regulations

In order to conform our regulations to the amendments made to the rural provider exception by section 6001(a)(1) of the Affordable Care Act, we are proposing to revise §411.356(c)(1) to specify that, in the case where the rural provider is a hospital, the hospital must meet the requirements of proposed new §411.362 no later than September 23, 2011.

Similarly, we are proposing to revise §411.356(c)(3) to add a new paragraph (iv) that provides that the hospital must meet the requirements in new §411.362 not later than

September 23, 2011. In new §411.362, we set forth the additional requirements for both exceptions as mandated by section 1877(i)(1) of the Act.

1. Physician Ownership and Provider Agreement

Section 1877(i)(1)(A) of the Act requires that, in order to use the rural provider and whole hospital exception under section 1877(D)(3)(d) of the Act, the hospital must have physician ownership or investment on December 31, 2010, and a provider agreement under section 1866 of the Act in effect on this date. We are proposing to incorporate these requirements in §411.362(b)(1) of the regulations.

Section 1877(i)(5) of the Act defines a "physician owner or investor" as a physician (or an immediate family member of such physician) with a direct or an indirect ownership or investment interest in the hospital. We are proposing to incorporate this statutory definition in §411.362(a)(1) of the regulations.

2. Limitation on Expansion of Facility Capacity

Section 1877(i)(1)(B) of the Act requires that the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after March 23, 2010, be no greater than the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on that date. However, section 1877(i)(3)(C) of the Act authorizes the Secretary to permit a physician-owned hospital to increase capacity above its "baseline number of operating rooms, procedure rooms, and beds." Section 1877(i)(3)(C)(iii) of the Act, as amended by section 1106(2)(B) of the HCERA, defines the term "baseline number of operating rooms, procedure rooms, and beds" to mean "the number of operating rooms, procedure rooms, and beds for which the 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 that date, but does have an agreement in effect on December 31, 2010, the effective date of such provider agreement)." Although section 1877(i)(1)(B) of the Act does not contain language regarding facility capacity as of the effective date of a provider agreement issued between March 23, 2010 and December 31, 2010, we must read sections 1877(i)(1)(B) and 1877(i)(3)(C)(iii) of the Act together and interpret them harmoniously. Accordingly, in proposed §411.362(b)(2), we specify that the hospital will be limited to the number of operating rooms, procedure rooms, and beds for which the hospital is licensed on March 23, 2010, or if the hospital did not have a provider agreement in effect as of that date, but does have an agreement in effect on December 31, 2010, the effective date of such provider agreement.

The limitation on expansion of facility capacity applies to operating rooms, procedure rooms, and beds for which the hospital is licensed. It is important to note that the limitation on expansion applies to operating rooms and procedure rooms regardless of whether a State licenses these rooms. Referrals are prohibited if made by physician owners and investors after facility expansion and prior to the Secretary's granting of an exception to the capacity restriction. Exceptions for expanding facility capacity will protect only those referrals made after the exception is granted.

Section 1877(i)(3)(G) of the Act specifies that "the term 'procedure rooms' includes rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include emergency rooms or departments (exclusive of rooms in which catheterizations, angiographies, angiograms, and

endoscopies are performed)." Under our proposed definition of procedure rooms at §411.362(a)(2), the term is limited to the types of rooms specified in the statute. Although the statute would permit us to define "procedure rooms" to include rooms where other services are performed, we are not proposing to do so at this time. We encourage public comments on whether "procedure rooms" should include rooms where additional services, such as CT or PET scans, or other services, are performed.

Section 1877(i)(3)(A) of the Act gives the Secretary until January 1, 2012 to promulgate regulations concerning the process for a hospital to apply for an exception and provides that the implementation of this process must be completed by February 1, 2012. We plan to issue a separate rulemaking document that will provide for implementation of this exceptions process.

3. Preventing Conflicts of Interest

Section 1877(i)(1)(C)(i) of the Act requires the hospital to submit to the Secretary an annual report containing a detailed description of the identity of each physician owner or investor and any other owners or investors of the hospital, and the nature and extent of all ownership and investment interests in the hospital. We plan to propose procedures for this reporting requirement in a separate rulemaking.

Section 1877(i)(1)(C)(ii)-(iv) of the Act requires hospitals to: (1) develop procedures requiring a referring physician owner or investor to disclose (in time to permit the patient to make a meaningful decision about receipt of care) his or her ownership interest to the patient and, if applicable, the treating physician's ownership or investment interest; (2) not condition any physician ownership or investment interests either directly

or indirectly on the physician making or influencing referrals to the hospital or otherwise generating business for the hospital; and (3) disclose on any public Web site for the hospital and in any public advertising that it is owned or invested in by physicians. Compliance with these three requirements must be achieved no later than September 23, 2011.

To incorporate these requirements into our regulations, we are proposing to: (1) add §411.362(b)(3)(ii)(A) to specify that a hospital must require each referring physician owner or investor to agree, as a condition of continued medical staff membership or admitting privileges, to provide written disclosure of his or her ownership or investment interest in the hospital (and, if applicable, the treating physician's ownership or investment interest in the hospital) to all patients the physician refers to the hospital, at the time the referral is made; (2) add §411.362(b)(3)(ii)(B) to specify that a hospital may not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital; and (3) add §411.362(b)(3)(ii)(C) to specify that the hospital must disclose on any public Web site for the hospital and in any public advertising that the hospital is owned or invested in by physicians.

Proposed §411.362(b)(3)(ii)(A) defines the procedures that a hospital must have in place to require its physician owners and investors to make certain patient disclosures. We do not believe the disclosures to be made by physicians will be burdensome. For example, a physician owner or investor could provide a written, form notice to each

patient that discloses the physician's ownership or investment interest in the hospital, informs the patient that his or her treating physician may have an ownership or investment interest in the hospital, and directs the patient to review an attached list identifying all other physician owners or investors in the hospital. This notice may be used by the patient to make a meaningful decision regarding his or her receipt of care.

We are soliciting public comments on several different issues relating to preventing conflicts of interest. First, we are seeking public comments on the benefits and drawbacks of our proposal, discussed above, relating to the procedures hospitals must have in place to require referring physician owners and investors to make the patient disclosures set forth in section 1877(i)(1)(C)(ii) of the Act. We are interested in receiving information about other methods and alternative approaches to address this issue and what should constitute sufficient hospital procedures to require such disclosures to a patient by a referring physician owner or investor.

Second, we are aware that a patient may have multiple conditions for which there are a variety of physician specialists who are responsible for different aspects of a patient's care, even though the statute refers to a single "treating physician." We are not proposing to define "treating physician." We will consider treating physicians to be those physicians who are responsible for any aspect of a patient's care or treatment. We welcome public comments on this approach.

Finally, we encourage public comments on the methods a hospital should be required to use in disclosing its physician ownership or investment in public advertising pursuant to section 1877(i)(1)(C)(iv) of the Act. For example, we are interested in

comments on whether a hospital should be required to disclose physician ownership or investment on its homepage, any particular page on its Web site (for example, an "About Us" page), or all pages on its Web site; the types of media that constitute, or do not constitute, public advertising; and whether a minimum font size should be required for the disclosure.

4. Ensuring *Bona Fide* Investment

Section 1877(i)(1)(D) of the Act sets forth seven different requirements related to ensuring *bona fide* investment in order for hospitals to qualify for the rural provider and whole hospital exceptions set forth in the physician self-referral law. First, the percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate may not exceed such percentage as of March 23, 2010. Second, any ownership or investment interests that the hospital offers to a physician owner or investor must not be offered on more favorable terms than the terms offered to a person who is not a physician owner or investor. Third, the hospital (or any owner or investor in the hospital) must not directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor. Fourth, the hospital (or any owner or investor in the hospital) must not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any individual physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital. Fifth, ownership or investment returns must be distributed to each owner or investor in the hospital in an amount that is directly

proportional to the ownership or investment interest of such owner or investor in the hospital. Sixth, physician owners and investors must not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital. Lastly, the hospital must not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to an individual who is not a physician owner or investor. We note that additional or different factors may be relevant to a determination of whether an investment is *bona fide* for purposes of complying with other laws, including fraud and abuse laws.

We are proposing to add §411.362(b)(4) to incorporate these provisions in our regulations. We recognize that section 1877(i)(1)(A) of the Act provides that the hospital must have had physician ownership or investment on December 31, 2010, while section 1877(i)(1)(D)(i) of the Act assumes the existence of physician ownership or investment on March 23, 2010 and further provides that the percentage of the total value of physician ownership or investment interests held in the hospital, in the aggregate, on that date must not increase. Reading these provisions together, we conclude the following: (i) if a hospital had no physician ownership or investment as of March 23, 2010, it will not qualify for the whole hospital or rural provider exceptions if it adds any physician owners or investors after that date; and (ii) if a hospital had physician ownership or investment as of March 23, 2010, it may reduce the number of physician owners or investors, provided

that the percentage of the total value of physician ownership or investment interests, in the aggregate, remains the same or decreases.

The second through seventh requirements tied to ensuring *bona fide* investment (sections 1877(i)(1)(D)(ii) through 1877(i)(1)(D)(vii) of the Act) do not specify any deadlines for compliance. Accordingly, compliance with the second through seventh requirements must be achieved no later than September 23, 2011.

If we determine that further guidance related to any aspect of section 1877(i)(1)(D) of the Act is necessary, we will provide clarification in future rulemaking. Furthermore, a hospital may request an advisory opinion (pursuant to §§411.370 through 411.389) for a determination of whether an existing or proposed arrangement meets the requirements for hospitals to ensure that investment is *bona fide*.

5. Patient Safety

Section 1877(i)(1)(E) of the Act, as added by the Affordable Care Act, requires a hospital that is owned or invested in by physicians to disclose to a patient before admission if it does not have a physician available on the premises to provide services during all hours that the hospital is providing services to such patient. Following this disclosure, the hospital must receive a signed acknowledgment of such fact from the patient. In addition, the hospital must have the capacity to provide assessment and initial treatment for patients and refer and transfer such patients to hospitals with the capability to treat the patients involved. We see no reason to treat the safety of inpatients differently than outpatients. Accordingly, given the language and purpose of the statute, we propose to apply these patient safety requirements to inpatients as well as outpatients.

Hospitals must meet these requirements no later than September 23, 2011. We are proposing to incorporate these provisions into our regulations at §411.362(b)(5).

6. Conversion from ASC

Section 1877(i)(1)(F) of the Act, as added by the Affordable Care Act, also prohibits the use of the rural provider and whole hospital exceptions by physician-owned hospitals that were converted from an ASC to a hospital on or after March 23, 2010. We are proposing to add §411.362(b)(6) to reflect this provision in our regulations.

7. Publication of Information Reported

As discussed in section XVIII.B. of this proposed rule, section 1877(i)(1)(C) of the Act, as added by the Affordable Care Act, requires the hospital to submit to the Secretary an annual report containing a detailed description of the identity of each physician owner or investor and any other owners or investors of the hospital and the nature and extent of all ownership and investment interests in the hospital. The process for collecting this information must be determined no later than September 23, 2011. Section 1877(i)(2) of the Act requires that the Secretary publish, and update on an annual basis, the information submitted by hospitals under section 1877(i)(1)(C) of the Act on the CMS Web site. As with the annual report requirement set forth in section XVIII.B. of this proposed rule, we are not making a proposal related to this provision at this time.

8. Enforcement

Section 6001(b)(1) of the Affordable Care Act requires the Secretary to establish policies and procedures to ensure compliance with the requirements described in section 1877(i) of the Act, and states that these policies and procedures may include

unannounced site reviews of hospitals. Section 6001(b)(2) of the Affordable Care Act requires the Secretary, beginning not later than May 1, 2012, to conduct audits to determine if physician-owned hospitals are in compliance with section 1877(i)(1) of the Act. We will comply with the statutory mandate, but are not proposing any regulations on this topic at this time.

D. Proposed Related Changes to Provider Agreement Regulations

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 regulations at 42 CFR Part 489, Subparts A and B (Provider Agreements and Supplier Approval). Section 1861(e) of the Act defines the term "hospital." Section 1861(e)(9) of the Act defines a hospital and authorizes the Secretary to establish requirements as determined necessary in the interest of patient health and safety. 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 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 amended the regulations at §489.3 governing Medicare provider agreements to define a "physician-owned hospital" as any participating hospital (including a CAH) in which a physician or immediate family member of a physician has an ownership or investment interest, unless the ownership or investment interest satisfies the exceptions at §411.356(a) or (b) regarding publicly-traded securities and mutual funds. In addition, we added a new provision at §489.20(u)(1) to require a physician-owned hospital to agree to furnish patients with written notice, in a manner reasonably designed to be understood by all patients, that it is physician-owned and that the list of physician owners is available upon request. Further, we added a new provision at §489.20(u)(2) to compel hospitals to require that all physician owners who are also members of the hospital's medical staff to disclose, in writing, their ownership interest in the hospital (and that of any immediate family member) to all patients they refer to the hospital, as a condition of continued medical staff membership. Patient disclosure is required at the time the physician makes a referral.

We also added a new provision to require that 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.

We are proposing to modify the Medicare provider agreement regulations in Subpart B of Part 489 in order to make the rules consistent with new §411.362, as required by the Affordable Care Act. Furthermore, incorporating the additional requirements of the Affordable Care Act is in the best interest of the health and safety of individuals who receive services in hospitals and CAHs. With respect to §489.20(u), we are proposing to: (1) add a provision in §489.20(u)(1)(ii) to specify that the hospital must disclose on any public Web site for the hospital and in any public advertising that it is owned or invested in by physicians; (2) amend §489.20(u)(2) to specify that a referring physician owner or investor must also disclose in writing, if applicable, the treating physician's ownership or investment interest in the hospital; and (3) add §489.20(u)(3) to specify that a hospital may not condition any physician ownership or investment interests either directly or indirectly on the physician making or influencing referrals to the hospital or otherwise generating business for the hospital.

Regarding §489.20(w), we are proposing to specify that, in the case of a hospital where a doctor of medicine or a doctor of osteopathy is not present in the hospital 24 hours per day, 7 days per week, before admitting a patient or providing an outpatient service, the hospital must receive a signed acknowledgment from the patient stating that

the patient understands that a physician may not be present during all hours services are rendered to the patient.

We encourage public comments on whether the changes to the provider agreement regulations (Part 489) are necessary or whether the amendments and additions made to the whole hospital and rural provider exceptions within subpart J of Part 411 of our regulations are sufficient to provide guidance relating to section 6001 of the Affordable Care Act.

XX. Files Available to the Public Via the Internet

A. Information in Addenda Related to the CY 2011 Hospital OPPS

Addenda A and B to this proposed rule provide various data pertaining to the proposed CY 2011 payment for items and services under the OPPS. Addendum A, which includes a list of all proposed APCs to be payable under the OPPS, and Addendum B, which includes a list of all active HCPCS codes with their proposed CY 2011 OPPS payment status and comment indicators, are available to the public by clicking "Hospital Outpatient Regulations and Notices" on the CMS Web site at: http://www.cms.gov/HospitalOutpatientPPS/.

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 proposed APC assignment, identified as Addendum C.

Addendum D1 defines the payment status indicators that we are proposing to use in Addenda A and B. Addendum D2 defines the comment indicators that we are proposing to use in Addendum B. Addendum E lists the proposed HCPCS codes that we

propose would only be payable to hospitals as inpatient procedures and would not be payable under the OPPS. Addendum L contains the proposed out-migration wage adjustment for CY 2011. Addendum M lists the proposed HCPCS codes that would be members of a composite APC and identifies the composite APC to which each would be assigned. This addendum also identifies the proposed status indicator for the 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 proposed HCPCS codes included in Addendum M has a single procedure payment APC, listed in Addendum B, to which it would be 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 composite APCs.

These addenda and other supporting OPPS data files are available on the CMS Web site at: http://www.cms.gov/HospitalOutpatientPPS/.

B. Information in Addenda Related to the CY 2011 ASC Payment System

Addenda AA and BB to this proposed rule provide various data pertaining to the proposed CY 2011 payment for the covered surgical procedures and covered ancillary services for which ASCs may receive separate payment. Addendum AA lists the proposed ASC covered surgical procedures and the proposed CY 2011 payment

indicators and payment rates for each procedure. Addendum BB displays the proposed ASC covered ancillary services, and their proposed CY 2011 payment indicators and payment rates. All proposed ASC relative payment weights and payment rates for CY 2011 are a result of applying the revised ASC payment system methodology established in the final rule for the revised ASC payment system published in the **Federal Register** on August 2, 2007 (72 FR 42470 through 42548) to the CY 2011 OPPS and MPFS ratesetting information.

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.

Addendum EE (available only on the CMS Web site) lists the surgical procedures that we are proposing to exclude from Medicare payment if furnished in ASCs. The proposed excluded procedures listed in Addendum EE are surgical procedures that would be assigned to the OPPS inpatient list, would not be covered by Medicare, would be reported using a CPT unlisted code, or have been determined to pose a significant safety risk or are expected to require an overnight stay when performed in ASCs.

These addenda and other supporting ASC data files are included on the CMS Web site at: http://www.cms.gov/ASCPayment/. The MPFS data files are located at: http://www.cms.gov/PhysicianFeeSched/.

The links to all of the proposed FY 2011 IPPS wage index-related tables (that we are proposing to use for the CY 2011 OPPS) that were published in the June 2, 2010

supplemental FY 2011 IPPS/LTCH PPS proposed rule (75 FR 30918) are accessible on the CMS Web site at: http://www.cms.gov/AcuteInpatientPPS/WIFN.

XXI. Collection of Information Requirements

A. Legislative Requirement 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.

B. Proposed Requirements Specified in the Regulation Text

This proposed rule contains the following proposed information collection requirements specified in regulatory text:

1. ICRs Regarding Redistribution of Medical Residency Slots

Existing regulations at §413.78 outline the requirements for the determination of the total number of FTE residents in determining direct GME payments to hospitals.

Section XVII.B.2.c. of the preamble of this proposed rule discusses the requirement for hospitals that share the costs of resident training in nonprovider settings, as permitted by the Affordable Care Act, to count a proportional share of the time and to record that proportion in a written agreement. We are proposing that this proportion must be included on a distinct written agreement for hospitals that pay nonhospital sites concurrently, without a written agreement as described in existing regulations. The burden associated with this requirement is the time and effort put forth by the hospital to prepare a written agreement. We estimate it would take one hospital 15 minutes to meet this requirement. Hospitals that already have a written agreement with a nonhospital site may include the proportion on that existing agreement.

In section XVII.B.2.d. of the preamble of this proposed rule, we discuss the requirement under the Affordable Care Act for hospitals to maintain records of the amount of time that their residents spend training in nonhospital sites, and to compare that time to the time spent by their residents in nonprovider sites in a base year as the Secretary may specify. We believe that a large part of the information that hospitals would be required to record for the purposes of this provision is contained in rotation schedules, which all hospitals are already required to maintain. Therefore, we do not believe that this requirement poses an undue administrative burden for the purposes of the PRA.

Existing regulations at §412.105 and §413.79 outline the requirements for the determination of the weighted number of FTE residents for IME and direct GME payments to hospitals. In sections XVII.B.4. and 5. of the preamble of this proposed rule,

we discuss our proposals that a hospital seeking an adjustment to the limit on its unweighted resident count under section 5503 or section 5506 of the Affordable Care Act must provide documentation justifying the adjustment. Sections XVII.B.4. and 5. of the preamble of this proposed rule specify the information that a request would have to include. These requirements are exempt from the PRA in accordance with the provisions of the Affordable Care Act.

2. ICRs Regarding Basic Commitments of Providers (§489.20) and Additional Requirements Concerning Physician Ownership and Investment in Hospitals (§411.362)

Current §489.20(u)(1) states that, in the case of a physician-owned hospital as defined in §489.3, the hospital must furnish written notice to all patients at the beginning of their hospital stay or outpatient visit that the hospital is a physician-owned facility. The burden associated with the requirements in this section is the time and effort necessary for a hospital to furnish written notice to all patients that the hospital is a physician-owned hospital. Whereas this requirement is subject to the PRA, the associated burden is currently approved under OMB control number 0938-1034, with an expiration date of February 28, 2011.

Our proposed amendment to §489.20(u)(1) and proposed new §411.362(b)(3)(ii)(C) would require disclosure by a hospital on any public Web site for the hospital and in any public advertising that the hospital is owned or invested in by physicians. The burden associated with this disclosure requirement is the time and effort necessary for hospitals to draft and post such a disclosure on their Web sites (where applicable) and to include such a disclosure in any existing or future public advertising

that the hospitals may utilize. We estimate that 265 hospitals must comply with this requirement. In addition, we estimate that it will take each hospital 1 hour to develop and place this information on its Web site and/or in a public advertisement. The estimated annual hospital burden associated with placing the aforementioned information in Web sites, public advertisement, or both is 265 hours at a cost of $3,993.55. In addition, we estimate that it will take 30 minutes annually for a hospital to review and update the information contained in its Web site, public advertising or both. The estimated annual burden associated with the annual review and update of the information is 132.5 hours at a cost of $1,996.77.

Our proposed amendment to §489.20(u)(2) and proposed new §411.362(b)(3)(ii)(A) would require the hospital to have procedures in place to require that each referring physician agree, as a condition of his or her continued medical staff membership or admitting privileges, to provide written disclosure of his or her ownership or investment interest in the hospital (and, if applicable a treating physician's ownership or investment interest in the hospital) to all patients whom the physician refers to the hospital. These provisions impose a burden on both hospitals and physicians.

With respect to hospitals, the burden associated with this requirement is the time and effort necessary for hospitals to develop, draft, and implement changes to its medical staff bylaws and other policies governing admitting privileges. Approximately 265 hospitals would be required to comply with these requirements. We estimate that it will require a hospital's general counsel 2 hours to revise a hospital's medical staff bylaws

and policies governing admitting privileges. Therefore, the total annual hospital burden would be 530 hours at a cost of $32,875.90.

With respect to physicians, the burden associated with this requirement is the time and effort necessary for a referring physician owner or investor to develop a list of all other physician owners or investors in the hospital and draft a form notice to patients that discloses the referring physician's ownership or investment interest in the hospital, informs the patient that a treating physician(s) of the patient may have an ownership or investment interest in the hospital, and directs the patient to review a list identifying all other physician owners or investors in the hospital. This list may be used by patients in making their health care decisions. Under existing §489.20(u)(1), hospitals are currently required to provide a list of their physician owners or investors to patients upon request at the beginning of their inpatient stay or outpatient visit. Because hospitals already maintain lists of their owners and investors, we estimate that it will take each physician 1 hour annually to obtain such a list from the hospital, draft a disclosure notice, and make copies that will be distributed to patients. In addition, we estimate that it will take 30 seconds to provide the disclosure notice to each patient and an additional 30 seconds to record proof of disclosure in each patient's medical record.

Although we can estimate the number of physician-owned hospitals, we are unable to quantify the number of physicians (or their immediate family members) who possess an ownership or investment interest in hospitals. There are limited data available concerning physician ownership in hospitals. The studies to date, including those by CMS and the GAO, pertain to physician ownership in specialty hospitals (cardiac,

orthopedic, and surgical hospitals). These specialty hospitals published data concerning the average percentage of shares of direct ownership by physicians (less than 2 percent), indirect ownership through group practices, and the aggregate percentage of physician ownership, but did not publish the number of physician owners in these types of hospitals. More importantly, §489.20(u)(2) applies to physician ownership in any type of hospital. Our other research involved a review of enrollment data. However, the CMS Medicare enrollment application (CMS-855) requires physicians to report only those ownership interests that are 5 percent or more (direct or indirect), and thus, most physician ownership is not captured. While we acknowledge there is a burden associated with this ICR, we have no way to quantify this requirement's burden. Therefore, because we are unable to estimate the total physician burden associated with this reporting requirement, we are assigning 1 burden hour to this requirement and we are also seeking public comment pertaining to this burden allocation and will reevaluate this issue in the final rule stage of rulemaking.

Existing §489.20(w) requires hospitals, as defined in §489.24(b), to furnish all patients notice in accordance with §482.13(b)(2), 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. The notice must indicate how the hospital will meet the medical needs of any inpatient who develops an emergency medical condition, as defined in §489.24(b), at a time when there is no physician present in the hospital. The burden associated with this requirement is the time and effort necessary for each hospital to develop a standard notice to furnish to its patients. Although this

requirement is subject to the PRA, the associated burden is approved under OMB control number 0938-1034, with a current expiration date of February 28, 2011.

Our proposed new §§489.20(w)(2) and 411.362(b)(5)(i) would require that, following a hospital's disclosure to a patient that it does not have a physician available during all hours that the hospital is providing services to such patient, the hospital must obtain a signed acknowledgment from the patient stating that the patient understands that no physician is available for that period. The burden associated with this requirement is the time and effort necessary for each hospital to add an acknowledgment line to its current form, disclose the form to the patient, obtain the patient's signature, and copy and record the form in the patient's medical record. The requirements in proposed §489.20(w) would apply to all hospitals (not just physician-owned hospitals), as defined in §489.24(b). We estimate that there are approximately 2557 hospitals and CAHs that may not have a physician on-site at all times. We estimate that it will take each hospital 30 minutes to amend its current disclosure form to add an acknowledgment line, an additional 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. The estimated annual burden associated with developing an amended form, obtaining patient signatures, and copying and recording the form is 1,196,932.6 hours at a cost of $18,518,081.15.

C. Associated Information Collections Not Specified in Regulatory Text

In this proposed rule, we make reference to proposed associated information collection requirements that are not discussed in the regulation text contained in this document. The following is a discussion of those requirements.

1. Hospital Outpatient Quality Data Reporting Program (HOP QDRP)

As previously stated in section XVI. of this proposed rule, the quality data reporting program for hospital outpatient care, 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, the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program. Section 109(a) of the MIEA-TRHCA (Pub. L. 109-432) amended section 1833(t) of the Act by adding a new subsection (17) which affects the annual payment update factor applicable to OPPS payments for services furnished by hospitals in outpatient settings on or after January 1, 2009. Section 1833(t)(17)(A) of the Act states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) that fail to report data required for the quality measures selected by the Secretary in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act will incur a 2.0 percentage point reduction to their annual payment update factor. 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)(A)(ii) of the Act specifies that any reduction would apply only to the payment year involved and would not be taken into account in computing the applicable annual payment update factor for a subsequent payment year. 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.

2. HOP QDRP Quality Measures for the CY 2012, CY 2013 and CY 2014 Payment Determinations

In the CY 2009 final rule with comment period (73 FR 68766), we retained the seven chart-abstracted measure we used in CY 2009 and adopted 4 new claims-based imaging measures for use in CY 2010, bringing the total number to 11 measures. In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60637), we adopted the same 11 measures and the same data submission requirements related to the 7 data abstracted measures for CY 2011 payment determinations. For the CY 2012 payment update, we are proposing that hospitals continue to submit data for the existing 7 chart-abstracted measures (we would continue to use the 4 claims-based measures) and to add 1 new chart-abstracted AMI measure, 4 additional claims-based imaging efficiency measures, and 1 structural measure regarding Health IT. These 17 measures are listed in the table below. For the CY 2013 payment determination, we are proposing that hospitals continue to submit data for all of the nonclaims-based measures previously adopted for the CY 2012 payment determination (we would continue to use the claims-based measures previously adopted), and to adopt 1 new structural measure on tracking clinical results, and 6 new chart-abstracted measures for the CY 2013 payment determination on the topics of HOPD care transitions, and ED efficiency, for a total of 24 measures. For the CY 2014 payment determination, we are proposing that hospitals continue to submit data for all of the measures previously adopted for the CY 2013

payment determination (we would continue to use the claims-based measures previously adopted), and to adopt 6 new chart-abstracted measures on the topics of diabetes care and exposure time for procedures using fluoroscopy, for a total of 30 measures. These proposed measures are listed below.

Proposed HOP QDRP Measurement Sets 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
The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their Qualified/Certified EHR System as Discrete Searchable Data*
Preoperative Evaluation for Low Risk Non Cardiac Surgery Risk Assessment*
Use of Stress Echocardiography, SPECT MPI, and Cardiac Stress MRI post CABG*
Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)*
Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache*
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 *
Median Time from ED Arrival to ED Departure for Discharged ED Patients**
Transition Record with Specified Elements Received by Discharged Patients**
Tracking Clinical Results between Visits**
Door to Diagnostic Evaluation by a Qualified Medical Professional**
ED- Median Time to Pain Management for Long Bone Fracture **
ED- Patient Left Before Being Seen**
ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival **

Proposed HOP QDRP Measurement Sets to be Used for the CY 2012, CY 2013 and CY 2014 Payment Determinations
Diabetes Mellitus: Hemoglobin A1c Poor Control in Diabetic Patients***
Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetic Patients***
Diabetes Mellitus: High Blood Pressure Control in Diabetic Patients***
Diabetes Mellitus: Dilated Eye Exam in Diabetic Patients***
Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients***
Exposure Time Reported for Procedures Using Fluoroscopy***

* Proposed new measure for CY 2012 payment determination.
** Proposed new measure for CY 2013 payment determination.
*** Proposed new measure for CY 2014 payment determination.

For the CY 2012 payment determination, hospitals would submit data related to the 8 chart-abstracted measures and we would calculate the 8 claims-based measures using administrative paid claims data and not require additional hospital data submissions. For the structural measure, hospitals would enter data into a Web-based collection tool.

As part of the data submission process pertaining to the 17 measures listed above for the CY 2012 payment determination, hospitals must also complete and submit a notice of participation in the HOP QDRP. By submitting this document, hospitals agree that they will allow CMS to publicly report the quality measures as required by the HOP QDRP.

For the CY 2012 payment determination, the burden associated with this section is the time and effort associated with completing the notice of participation as well as collecting and submitting the data on the eight data abstracted measures and the one structural measure. We estimate that there will be approximately 3,200 respondents per year. For hospitals to collect and submit the information on the required measures, we

estimate it will take 35 minutes per sampled case. We estimate there will be a total of 930,000 cases per year, approximately 290 cases per year per respondent. The estimated annual burden associated with the aforementioned submission requirements for chart-abstracted data is 542,500 hours (930,000 cases per year x 0.583 hours/case). For the structural measure, we estimate that it will require 10 minutes per hospital for one instance per year; the estimated annual burden associated with this requirement is 533 hours (3200 hospitals x 0.167 hours per hospital).

We invite public comment on the burden associated with these information collection requirements.

3. Proposed HOP QDRP Validation Requirements

In addition to requirements for submitting of quality data, hospitals must also comply with the requirements for data validation in CY 2012. Similar to our proposed policy for the FY 2012 RHQDAPU program (75 FR 23991 through 23993), we are proposing to validate data from 800 randomly selected hospitals each year under the HOP QDRP, beginning with the CY 2012 payment determination. We note that, because the 800 hospitals would be selected randomly, every HOP QDRP-participating hospital would be eligible each year for validation selection. 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 has submitted less than 12 cases in one or more quarters, only those cases available will be validated.

The burden associated with the proposed CY 2012 requirement is the time and effort necessary to submit validation data to a CMS contractor. We estimate that it will take each of the 800 sampled hospitals approximately 12 hours to comply with these data submission requirements. To comply with the requirements, we estimate each hospital must submit 48 cases for the affected year for review. We estimate that 800 hospitals must comply with these requirements to submit a total of 38,400 charts across all sampled hospitals. The estimated annual burden associated with the data validation process for CY 2012 and subsequent years is 9,600 hours.

We invite public comment on this information collection requirement.

4. Proposed HOP QDRP 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 will apply 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. We are proposing to continue this process for the CY 2012 payment update with some modifications. We have proposed to eliminate a requirement that the reconsideration request form be signed by the hospital CEO to facilitate electronic submission of the form and reduce hospital burden. Under this proposed process, the hospitals would be required to meet all of the requirements specified in section XVI.E. of this proposed rule. While there is burden associated with filing a reconsideration request, section 5 CFR 1320.4 of the Paperwork Reduction Act of 1995 excludes collection activities during the conduct of

administrative actions such as redeterminations, reconsiderations, and/or appeals. Specifically, these actions are taken after the initial determination or denial of payment.

5. Additional Topics

While we are seeking OMB approval for the information collection requirements associated with the HOP QDRP and the data validation processes, we also are seeking public comment on several issues that may ultimately affect the burden associated with HOP QDRP and the data validation processes. Specifically, this proposed rule lists proposed quality measures for CY 2012 through CY 2014 payment determinations as well as other possible quality measures under consideration for CY 2013 and subsequent years. We also are soliciting public comments to explore the use of registries to comply with the HOP QDRP submission requirements, the use of EHRs as a data submission tool, the use of a standardized process for the retirement of HOP QDRP quality measures, the continued use of an extraordinary circumstance extension or waiver for reporting quality data, and the implementation of additional data validation conditions.

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–1504–P)

Fax: (202) 395-6974; or

E-mail: OIRA_submission@omb.eop.gov.

XXII. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "**DATES**" section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document(s).

XXII. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

1. Executive Order 12866

Executive Order 12866 directs 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). A regulatory impact analysis (RIA) must be prepared for major rules that have economically significant effects ($100 million or more in any 1 year) or adversely affect in a material way the

economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal government or communities (58 FR 51741).

We estimate that the effects of the 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 2011 compared to CY 2010 to be approximately $3.9 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 55 of this proposed rule displays the redistributional impact of the CY 2011 proposed changes on OPPS payment to various groups of hospitals.

We estimate that the effects of the ASC provisions that would be implemented by this proposed rule for the ASC payment system would not exceed $100 million in any 1 year and, therefore, are not economically significant. 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 2011 compared to CY 2010 to be approximately $0. However, because this proposed rule for the ASC payment system substantially affects ASCs, 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 57 and Table 58 of this proposed rule

display the redistributional impact of the CY 2011 changes on ASC payment, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

2. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Many hospitals, other providers, ASCs, and other suppliers are considered to be small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (hospitals having revenues of $34.5 million or less in any 1 year and ASCs having revenues of $10 million or less in any 1 year). (For details on the latest standards for health care providers, we refer readers the SBA's Web site at: http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf (refer to the 620000 series).)

For purposes of the RFA, we have determined that many hospitals and most ASCs would be considered small entities according to the SBA size standards. Individuals and States are not included in the definition of a small entity. Therefore, the Secretary has determined that this proposed rule would have a significant impact on a substantial number of small entities. Because we acknowledge that many of the affected entities are small entities, the analyses presented throughout this proposed rule constitute our proposed regulatory flexibility analysis. Therefore, we are soliciting public comments on

our estimates and analyses of the impact of this proposed rule on those small entities.

3. Small Rural Hospitals

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we now define a small rural hospital as a hospital that is located outside an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21) designated hospitals in certain New England counties as belonging to the adjacent urban areas. Thus, for OPPS purposes, we continue to classify these hospitals as urban hospitals. We believe that the proposed changes to the OPPS in this proposed rule would affect both a substantial number of rural hospitals as well as other classes of hospitals and that the effects on some may be significant. Also, the changes to the ASC payment system in this proposed rule would affect rural ASCs. Therefore, the Secretary has determined that this proposed rule would have a significant impact on the operations of a substantial number of small rural hospitals.

4. Unfunded Mandates

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.

5. Federalism

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 55 below, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.2 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 provisions related to payments to ASCs in CY 2011 would not affect payments to any ASCs owned by government entities.

The following analysis, 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.

B. Effects of OPPS Changes in This Proposed Rule

We are proposing to make several changes to the OPPS that are required by the statute. 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 revise, not less often than annually, the wage index and other adjustments, including pass-through payments and outlier payments. In addition, we must review the clinical integrity of payment groups and weights at least annually. Accordingly, 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, 2011, 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 from January 1, 2009, through December 31, 2009, and updated cost report information. We are proposing to continue the current payment adjustment for rural SCHs, including EACHs. We are proposing an adjustment for cancer hospitals identified under 1886(d)(1)(B)(v) of the Act in accordance with section 3138 of the Affordable Care Act, as amended by HCERA. Finally, we list the 18 drugs and biologicals in Table 20 of this proposed rule that we are proposing to remove from pass-through payment status for CY 2011.

Under this proposed rule, we estimate that the proposed update change to the conversion factor and other adjustments (but not including the effects of outlier

payments, pass through estimates, the expiration of section 508 wages on September 30, 2010, and the application of the frontier wage adjustment for CY 2011) as provided by the statute would increase total OPPS payments by 2.1 percent in CY 2011. 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 do change the distribution of payments within the budget neutral system as shown in Table 55 below and described in more detail in this section. We also estimate that the total change in payments between CY 2010 and CY 2011, considering all payments, including changes in estimated total outlier payments, pass through payments, the expiration of additional money for specified section 508 reclassification and special exception wages indices, and the application of the frontier adjustment outside of budget neutrality, would increase total OPPS payments by 2.2 percent.

1. Alternatives Considered

Alternatives to the changes we are making and the reasons that we have chosen the options are discussed throughout this proposed rule. Some of the major issues discussed in this proposed rule and the options considered are discussed below.

a. Alternatives Considered for the Extension of Waiver of Deductible to Services Furnished in Connection with or in Relation to a Colorectal Screening Test that becomes Diagnostic

Section 4104(c)(2)of the Affordable Care Act waives the deductible with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test. We are proposing for CY 2011 that the deductible be waived for all surgical services furnished on the same date as a planned screening colonoscopy, planned flexible sigmoidoscopy, or barium enema as being furnished in connection with, as a result of, and in the same clinical encounter as the screening test. As discussed in detail in XII.B.3 of this rule, we are proposing to implement this provision by creating a HCPCS modifier that hospitals would append to the diagnostic procedure code that is reported instead of the screening colonoscopy or screening flexible sigmoidoscopy HCPCS code or as a result of the barium enema when the screening test becomes a diagnostic service. The claims processing system would respond to the modifier by waiving the deductible for all surgical services on the same date as the diagnostic test. Coinsurance or copayment would continue to apply to the diagnostic test and other services furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

We considered three alternatives for the extension of waiver of deductible to services furnished in connection with or in relation to a colorectal screening test that