DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 416, and 419

[CMS–1404–FC; CMS–3887–F; CMS–3835–F–1]

RIN 0938–AP17; RIN 0938–AL80; RIN 0938–AH17

Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payment Rates; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants—Clarification of Provider and Supplier Termination Policy Medicare and Medicaid Programs: Changes to the Ambulatory Surgical Center Conditions for Coverage

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

ACTION: Final rule with comment period; final rules.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system, and to implement a number of changes made by the Medicare Improvement for Patients and Providers Act of 2008. In this final rule with comment period, we describe the changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. These changes are applicable to services furnished on or after January 1, 2009.

In addition, this final rule with comment period updates the revised Medicare ambulatory surgical center (ASC) payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In this final rule with comment period, we set forth the applicable relative payment weights and amounts for services furnished in ASCs, specific HCPCS codes to which these changes apply, and other pertinent ratesetting information for the CY 2009 ASC payment system. These changes are applicable to services furnished on or after January 1, 2009.

In this document, we are responding to public comments on a proposed rule and finalizing updates to the ASC Conditions for Coverage to reflect current ASC practices and new requirements in the conditions to promote and protect patient health and safety.

Further, this final rule also clarifies policy statements included in responses to public comments set forth in the preamble of the March 30, 2007 final rule regarding the Secretary's ability to terminate Medicare providers and suppliers (that is, transplant centers) during an appeal of a determination that affects participation in the Medicare program.

DATES: *Effective Dates:* The provisions of this rule are effective January 1, 2009, except for amendments to 42 CFR 416.2, 416.41 through 416.43, and 416.49 through 416.52 are effective on May 18, 2009. The policy clarification set forth in section XVIII of the preamble of this rule is effective December 18, 2008.

Comment Period: We will consider comments on the payment classifications assigned to HCPCS codes identified in Addenda B, AA, and BB to this final rule with comment period with the ''NI'' comment indicator, and on other areas specified throughout this rule, received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EST on December 29, 2008.

Application Deadline—New Class of New Technology Intraocular Lenses: Request for review of applications for a new class of new technology intraocular lenses must be received by 5 p.m. EST on March 2, 2009.

ADDRESSES: In commenting, please refer to file code CMS–1404–FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the file code to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–1404–FC, P.O. Box 8013, Baltimore, MD 21244–1850.

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

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–1404–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

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

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

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

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

Applications for a new class of new technology intraocular lenses: Requests for review of applications for a new class of new technology intraocular lenses must be sent by regular mail to: ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Alberta Dwivedi, (410) 786–0378, Hospital outpatient prospective payment issues.

Dana Burley, (410) 786–0378, Ambulatory surgical center issues.

Suzanne Asplen, (410) 786–4558, Partial hospitalization and community mental health center issues.

Sheila Blackstock, (410) 786–3502, Reporting of quality data issues.

Jacqueline Morgan, (410) 786–4282, Joan A. Moliki, (410) 786–5526, Steve Miller, (410) 786–6656, and Jeannie Miller, (410) 786–3164, Ambulatory

surgical center Conditions for Coverage issues.

Marcia Newton, (410) 786–5265, and Karen Tritz, (410) 786–8021, Clarification of provider and supplier termination policy issues.

SUPPLEMENTARY INFORMATION:

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

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

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Alphabetical List of Acronyms Appearing in This Final Rule With Comment Period

AAAASF American Association for Accreditation of Ambulatory Surgical Facilities
AAAHC Accreditation Association for Ambulatory Health Care
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, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BCA Blue Cross Association
BCBSA Blue Cross and Blue Shield Association
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Public Law 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
CfC Condition for Coverage
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services
CoP Condition of participation
CORF Comprehensive outpatient rehabilitation facility
CPT [Physicians'] Current Procedural Terminology, Fourth Edition, 2007, copyrighted by the American Medical Association
CRNA Certified registered nurse anesthetist
CY Calendar year
DMEPOS Durable medical equipment, prosthetics, orthotics, and supplies
DMERC Durable medical equipment regional carrier
DRA Deficit Reduction Act of 2005, Public Law 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, Public Law 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
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, Public Law 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
IDE Investigational device exemption
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 Contractors
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, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 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
PPI Producer Price Index
PPS Prospective payment system
PPV Pneumococcal pneumonia vaccine
PRA Paperwork Reduction Act
QAPI Quality Assessment and Performance Improvement
QIO Quality Improvement Organization
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, Public Law 97–248
TOPS Transitional outpatient payments
USPDI United States Pharmacopoeia Drug Information
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. The provisions relating to the OPPS are included in sections I. through XIV., XVI., XVII., and XIX. through XXIII. of this final rule with comment period and in Addenda A, B, C (Addendum C is available on the Internet only; we refer readers to section XIX. of this final rule with comment period), D1, D2, E, L, and M to this final rule with comment period. The provisions related to the revised ASC payment system are included in sections XV. and XIX. through XXIII. of this final rule with comment period and in Addenda AA, BB, DD1, DD2, and EE

to this final rule with comment period. (Addendum EE is available on the Internet only; we refer readers to section XIX. of this final rule with comment period.)

In this document, we also address changes to the ASC Conditions for Coverage (CfCs). The provisions relating to the ASC CfCs are included in sections XV., XIX., XX.B., and XXIII. of this document. In addition, in this document, we clarify policy regarding the Secretary's ability to terminate Medicare providers and suppliers (in this case, transplant centers) during an appeal of a determination that affects participation in the Medicare Program. This clarification is included in section XVIII. of this document.

Table of Contents

I. Background for the OPPS

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

When the Medicare statute was originally 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 Social Security Act (the Act) authorizing implementation of a PPS for hospital outpatient services.

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 Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106–554) made further changes in the OPPS. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108–173) also amended Section 1833(t) of the Act. The Deficit Reduction Act (DRA) of 2005 (Pub. L. 109–171), enacted on February 8, 2006, also made additional changes in the OPPS. In addition, 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, made further changes in the OPPS. Further, the Medicare, Medicaid, and SCHIP Extension Act (MMSEA) of 2007 (Pub. L. 110–173), enacted on December 29, 2007, made additional changes in the OPPS. We also note that the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 (Pub. L. 110–275), enacted on July 15, 2008, made further changes to the OPPS. A discussion of these changes related to the MMSEA are included in sections I.E., II.C., V., and VII. of this final rule with comment period and those related to the MIPPA are included in sections I.F., II.C., II.E.1., V., VII., and XII.C.

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.

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 final rule with comment period. Section 1833(t)(1)(B)(ii) of the Act provides for Medicare 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. Section 611 of Public Law 108–173 added provisions for Medicare coverage for an initial preventive physical examination, subject to the applicable deductible and coinsurance, as an outpatient department service, payable under the OPPS.

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, services and items 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 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. Section 614 of Public Law 108–173 amended section 1833(t)(1)(B)(iv) of the Act to exclude payment for screening and diagnostic mammography services from the OPPS. 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 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. We published in the **Federal Register** on November 27, 2007 the CY 2008 OPPS/ASC final rule with comment period (72 FR 66580). 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 2008 OPPS on the basis of claims data from January 1, 2006, through December 31, 2006, and to implement certain provisions of Public Law 108–173 and Public Law 109–171. In addition, we responded to public comments received on the provisions of the November 26, 2006 final rule with comment period (71 FR 67960) pertaining to the APC assignment of HCPCS codes identified in Addendum B to that rule with the new interim (NI) comment indicator; and public comments received on the August 2, 2007 OPPS/ASC proposed rule for CY 2008 (72 FR 42628).

Subsequent to publication of the CY 2008 OPPS/ASC final rule with comment period, we published in the **Federal Register** on February 22, 2008, a correction notice (73 FR 9860) to correct certain technical errors in the CY 2008 OPPS/ASC final rule with comment period.

On July 18, 2008, we issued in the **Federal Register** (73 FR 41416) a proposed rule for the CY 2009 OPPS/ASC payment system to implement statutory requirements and changes arising from our continuing experience with both systems. Subsequent to issuance of the CY 2009 OPPS/ASC proposed rule, we published in the **Federal Register** on August 11, 2008 a correction notice (73 FR 46575) to replace Table 30 included the CY 2009 OPPS/ASC proposed rule.

D. APC Advisory Panel

1. Authority of the APC Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of the BBRA, and redesignated by section 202(a)(2) of the BBRA, 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 Advisory Panel on Ambulatory Payment Classification (APC) Groups (the APC Panel), discussed under section I.D.2. of this final rule with comment period, 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 three times: On November 1, 2002; on November 1, 2004; and on November 21, 2006. 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 Officer (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, February 28, and March 1, 2001. Since the initial meeting, the APC Panel has held 15 subsequent meetings, with the last meeting taking place on August 27 and 28, 2008. 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. At its March 2008 meeting, the APC Panel recommended that the Observation and Visit Subcommittee's name be changed to the ''Visits and Observation Subcommittee.'' As stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41421), we are accepting this recommendation and are referring to the subcommittee by its new name, as appropriate, throughout this final rule with comment period. Thus, 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 their continuation as subcommittees was last approved at the August 2008 APC Panel meeting. At that meeting, the Panel recommended that the work of these three subcommittees continue, and we are accepting that recommendation. All subcommittee recommendations are discussed and voted upon by the full APC Panel.

Discussions of the recommendations resulting from the APC Panel's March and August 2008 meetings are included in the sections of this final rule that are specific to each recommendation. For

discussions of earlier APC Panel meetings and recommendations, we refer readers to previously published hospital OPPS final rules, the Web site mentioned earlier in this section, or the FACA database at *http://fido.gov/facadatabase/public.asp.*

During the comment period for the CY 2009 OPPS/ASC proposed rule, we received several public comments regarding representation on the APC Panel.

Comment: Several commenters requested that CMS include a designated ASC representative on the APC Panel. The commenters believed that, because the ASC payment system is based on the same APC groups and relative payment weights as the OPPS, ASC representation on the APC Panel would ensure input from representatives of all the care settings providing surgical services whose payment groups and payment weights are affected by the OPPS.

Response: We acknowledge that the revised ASC payment system provides Medicare payment to ASCs for surgical procedures that is based, in most cases, on the relative payment weights of the OPPS. However, CMS is statutorily required to have an appropriate selection of representatives of ''providers'' as members of the APC Panel.

Specifically, the current APC Panel charter requires that ''Each Panel member must be employed full-time by a hospital, hospital system, or other Medicare provider subject to payment under the OPPS,'' which does not include ASCs because ASCs are not providers. We refer readers to section 1833(t)(9)(A) of the Act and § 400.202 of our regulations for specific requirements and definitions. The charter must comply with the statute, which does not include representatives of suppliers on the APC Panel. However, we understand the concerns of commenters regarding their interest in ASC input on the APC Panel now that the ASC payment system is based on the OPPS relative payment weights.

E. Provisions of the Medicare, Medicaid, and SCHIP Extension Act of 2007

The Medicare, Medicaid and SCHIP Extension Act (MMSEA) of 2007 (Pub. L. 110–173), enacted on December 29, 2007, includes the following provisions that affect the OPPS and the revised ASC payment system:

1. Increase in Physician Payment Update

Section 101 of the MMSEA provided a 0.5 percent increase in the physician payment update from January 1, 2008 through June 30, 2008; revised the Physician Assistance and Quality Initiative Fund, and extended through 2009 the physician quality reporting system. We refer readers to section XV. of this final rule with comment period for discussion of the effect of this provision on services paid under the revised ASC payment system.

2. Extended Expiration Date for Cost-Based OPPS Payment for Brachytherapy Sources and Therapeutic Radiopharmaceuticals

Section 106 of the MMSEA amended section 1833(t)(16)(C) of the Act, as amended by section 107 of the MIEA–TRCHA, to extend for an additional 6 months, through June 30, 2008, payment for brachytherapy devices at hospitals' charges adjusted to costs and to mandate that the same cost-based payment methodology apply to therapeutic radiopharmaceuticals for the same extended payment period. We refer readers to sections V.B.4. and VII. of this final rule with comment period for discussion of this provision. We also note that section 142 of Public Law 110–275 further extended this provision, as discussed in section I.F.4. of this final rule with comment period.

3. Alternative Volume Weighting in Computation of Average Sales Price (ASP) for Medicare Part B Drugs

Section 112 of the MMSEA amended section 1847A(b) of the Act to provide for application of alternative volume weighting in computing the ASP for payment of Medicare Part B multiple source and single source drugs furnished after April 1, 2008, and for a special rule, beginning April 1, 2008, for payment of single source drugs or biologicals treated as a multiple source drug. This provision is discussed in section V. of this final rule with comment period.

4. Extended Expiration Date for Certain IPPS Wage Index Geographic Reclassifications and Special Exceptions

Section 117 of the MMSEA extended through September 30, 2008, both the reclassifications that were extended by section 106 of MIEA–TRCHA as well as certain special exception wage indices referenced in the FY 2005 IPPS final rule (69 FR 49105 and 49107). We refer readers to section II.C. of this final rule with comment for discussion of this provision. We also note that section 124 of Public Law 110–275 further extended this provision through September 30, 2009, as discussed under section I.F.2. of this final rule with comment period.

F. Provisions of the Medicare Improvements for Patients and Providers Act of 2008

The Medicare, Improvements for Patients and Providers Act (MIPPA) of 2008 (Pub. L. 110–275), enacted on July 15, 2008, includes the following provisions that affect the OPPS and the revised ASC payment system:

1. Improvements to Coverage of Preventive Services

Section 101(b) of the MIPPA amended section 1861 of the Act, as amended by section 114 of the MMSEA, to make several changes to the Initial Preventive Physical Examination (IPPE) benefit, including waiving the deductible and extending the period of eligibility for an IPPE from 6 months to 12 months after the date of the beneficiary's initial enrollment in Medicare Part B. Section 101(b) of the MIPPA also removed the screening electrocardiagram (EKG) as a mandatory requirement that is part of the IPPE and required that there be education, counseling, and referral for an EKG, as appropriate, for a once-in-a-lifetime screening EKG performed as a result of a referral from an IPPE. The facility service for the screening EKG (tracing only) is payable under the OPPS when it is the result of a referral from an IPPE. The amendments apply to services furnished on or after January 1, 2009. We refer readers to section XII.C. of this final rule for discussion of the HCPCS codes to be used for the IPPE and screening EKG and the OPPS payment rates for services under this provision for CY 2009.

2. Extended Expiration Date for Certain IPPS Wage Index Geographic Reclassifications and Special Exceptions

Section 124 of the MIPPA extended through September 30, 2009 the hospital wage index reclassifications for hospitals reclassified under section 508 of the MMA. MIPPA also extended through the last date of the extension of the reclassifications under section 106(a) of the MIEA–TRHCA certain special exception wage indices referenced in the FY 2005 IPPS final rule (69 FR 49105 and 49107) and that were extended by section 117(a)(2) of the MMSEA. We refer readers to section II.C. of this final rule with comment period for discussion of this provision.

3. Increase in Physician Payment Update

Section 131 of MIPPA increased the conversion factor by 1.1 percent for CY 2009 and required that CY 2008 and CY 2009 payment updates have no effect on payment rates for CY 2010 and subsequent years under the MPFS. We

refer readers to section XV.F. of this final rule with comment period for discussion of the effect of this provision on payment for covered office-based surgical procedures and covered ancillary services paid under the ASC payment system.

4. Extension of Expiration Date for Cost-Based OPPS Payment for Brachytherapy and Therapeutic Radiopharmaceuticals

Section 142 of the MIPPA amended section 1833(t)(16)(C) of the Act, as amended by section 106(a) of the MMSEA, and further extended the payment period for brachytherapy devices sources and therapeutic radiopharmaceuticals based on hospital's charges adjusted to cost through December 31, 2009. We refer readers to sections V.B.4. and VII. of this final rule with comment period for discussions of this provision. We also refer readers to section XV.F. of this final rule with comment period for discussion of the effect of this provision on covered ancillary services paid under the ASC payment system.

5. Extension and Expansion of the Medicare Hold Harmless Provision Under the OPPS for Certain Hospitals

Section 147 of the MIPPA amended section 1833(t)(7)(D)(i) of the Act by extending the hold harmless payments (85 percent of the difference between the prospective payment system amount under the OPPS and the pre-BBA amount) for covered OPD services furnished by rural hospitals with 100 beds or less through December 31, 2009. It also expanded the same hold harmless payments to SCHs with 100 beds or fewer for covered OPD services furnished on or after January 1, 2009, and before January 1, 2010. We refer readers to section II.E. of this final rule with comment period for discussion of this provision.

G. Summary of the Major Contents of the CY 2009 OPPS/ASC Proposed Rule

A proposed rule appeared in the July 18, 2008 **Federal Register** (73 FR 41416) that set forth proposed changes to the Medicare hospital OPPS for CY 2009 to implement statutory requirements and changes arising from our continuing experience with the system and to implement certain new statutory provisions. In addition, we proposed changes to the revised Medicare ASC payment system for CY 2009, including updated payment weights and covered ancillary services based on the proposed OPPS update. Finally, 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 2010 and subsequent calendar years, the 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 CY 2009, in accordance with the statutory requirement. The following is a summary of the major changes included in the CY 2009 OPPS/ASC proposed rule:

1. Updates Affecting OPPS Payments

In section II. of the 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 changes in the amounts and factors for calculating the full annual update increase to the conversion factor.
- The proposed retention of our current policy to use the IPPS wage indices to adjust, for geographic wage differences, the portion of the OPPS payment rate and the copayment standardized amount attributable to labor-related cost.
- The proposed update of statewide average default CCRs.
- The proposed application of hold harmless transitional outpatient payments (TOPs) for certain small rural hospitals.
- 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. OPPS Ambulatory Payment Classification (APC) Group Policies

In section III. of the proposed rule, we discussed the proposed additions of new procedure codes to the APCs; our proposal to establish a number of new APCs; and our analyses of Medicare claims data and certain recommendations of the APC Panel. We also discussed the application of the 2 times rule and proposed exceptions to it; proposed changes to specific APCs; and proposed movement of procedures from New Technology APCs to clinical APCs.

3. OPPS Payment for Devices

In section IV. of the proposed rule, we discussed 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. OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

In section V. of the proposed rule, we discussed proposed CY 2009 OPPS payment for drugs, biologicals, and radiopharmaceuticals, including the proposed payment for drugs, biologicals, and radiopharmaceuticals with and without pass-through status.

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

In section VI. of the proposed rule, we discussed the estimate of CY 2009 OPPS transitional pass-through spending for drugs, biologicals, and devices.

6. OPPS Payment for Brachytherapy Sources

In section VII. of the proposed rule, we discussed our proposal concerning coding and payment for brachytherapy sources.

7. OPPS Payment for Drug Administration Services

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

8. OPPS Payment for Hospital Outpatient Visits

In section IX. of the proposed rule, we set forth our proposed policies for the payment of clinic and emergency department visits and critical care services based on claims paid under the OPPS.

9. Payment for Partial Hospitalization Services

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

10. Procedures That Will Be Paid Only as Inpatient Procedures

In section XI. of the proposed rule, we discussed the procedures that we proposed to remove from the inpatient list and assign to APCs.

11. OPPS Nonrecurring Technical and Policy Clarifications

In section XII. of the proposed rule, we set forth our nonrecurring technical issues and policy clarifications.

12. OPPS Payment Status and Comment Indicators

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

13. OPPS Policy and Payment Recommendations

In section XIV. of the proposed rule, we addressed recommendations made by the Medicare Payment Advisory Commission (MedPAC) in its June 2007 and March 2008 reports to Congress, by the APC Panel regarding the OPPS for CY 2009, and by the Office of the Inspector General (OIG) in its June 2007 report.

14. Update of the Revised Ambulatory Surgical Center Payment System

In section XV. of the proposed rule, we discussed the proposed update of the revised ASC payment system payment rates for CY 2009.

15. Reporting of Hospital Outpatient Quality Data for Annual Hospital Payment Rate Updates and CY 2009 Payment Reduction

In section XVI. of the proposed rule, we discussed the proposed quality measures for reporting hospital outpatient quality data for the annual payment update factor for CY 2010 and subsequent calendar years, set forth the requirements for data collection and submission for the annual payment update, and proposed a reduction in the OPPS payment for hospitals that fail to meet the HOP QDRP requirements for CY 2009.

16. Healthcare-Associated Conditions

In section XVII. of the proposed rule, we discussed considerations related to potentially extending the principle of Medicare not paying more for the preventable healthcare-associated conditions acquired during inpatient stays paid under the IPPS to other Medicare payment systems for healthcare-associated conditions that occur or result from care in other settings.

17. Regulatory Impact Analysis

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

H. Public Comments Received in Response to the CY 2009 OPPS/ASC Proposed Rule

We received approximately 2,390 timely pieces of correspondence containing multiple comments on the CY 2009 OPPS/ASC proposed rule. We note that we received some comments that were outside the scope of the CY 2009 OPPS/ASC proposed rule, including public comments on new CY 2009 HCPCS codes that were not presented in the CY 2009 OPPS/ASC proposed rule. These comments are not addressed in this CY 2009 OPPS/ASC final rule with comment period. New CY 2009 HCPCS codes are designated with comment indicator ''NI'' in Addenda B, AA, and BB to this final rule with comment period, to signify that their CY 2009 interim OPPS and/or ASC treatment is open to public comment on this final rule with comment period. Summaries of the public comments that are within the scope of the proposals and our responses to those comments are set forth in the various sections of this final rule with comment period under the appropriate headings.

I. Public Comments Received on the November 27, 2007 OPPS/ASC Final Rule With Comment Period

We received approximately 507 timely items of correspondence on the CY 2008 OPPS/ASC final rule with comment period, some of which contained multiple comments on the interim APC assignments and/or status indicators of HCPCS codes identified with comment indicator ''NI'' in Addendum B to that final rule with comment period. Summaries of those public comments on topics open to comment in the CY 2008 OPPS/ASC final rule with comment period and our responses to them are set forth in the various sections of this final rule with comment period under the appropriate headings.

J. Proposed Rule on ASC Conditions for Coverage

On August 31, 2007, we published in the **Federal Register** (72 FR 50470) a proposed rule to update the ASC Conditions for Coverage (CfCs) by revising some of the definitions and revising the CfCs on governing body and management and laboratory and radiologic services to reflect current ASC practices; and to add several new CfCs on quality assessment and performance improvement, patient rights, and patient admission, assessment, and discharge to promote and protect patient health and safety.

We received 30 timely items of correspondence on this proposed rule. We present a summary of the provisions of the proposed rule, a summary of the public comments received and our responses, and the final policy provisions in section XV.B. of the preamble of this document. (Hereinafter, we refer to this proposed rule as the 2007 ASC CfCs proposed rule.)

K. Medicare Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Programs To Perform Transplants—Clarification of Provider and Supplier Termination Policy

In section XVIII. of this document, we are clarifying policy set forth in responses to public comments on a March 30, 2007 final rule (72 FR 15198) regarding the Secretary's ability to terminate Medicare providers and suppliers (in this case, transplant centers) during an appeal of a determination that affects participation in the Medicare program.

II. Updates Affecting OPPS Payments

A. 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. As discussed in the November 13, 2000 interim final rule (65 FR 67824 through 67827), except for some reweighting due to a small number of APC changes, these relative payment weights continued to be in effect for CY 2001.

For CY 2009, we proposed to use the same basic methodology that we described in the April 7, 2000 OPPS final rule with comment period to recalibrate the APC relative payment weights for services furnished on or after January 1, 2009, and before January 1, 2010 (CY 2009). That is, we proposed to recalibrate the relative payment weights for each APC based on claims and cost report data for outpatient services. We proposed to use the most recent available data to construct the database for calculating APC group weights. Therefore, for the purpose of recalibrating the final APC relative payment weights for CY 2009, we used approximately 140 million final action

claims for hospital outpatient department (HOPD) services furnished on or after January 1, 2007, and before January 1, 2008. (For exact counts of claims used, we refer readers to the claims accounting narrative under supporting documentation for this final rule with comment period on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/*.)

Of the 140 million final action claims for services provided in hospital outpatient settings used to calculate the CY 2009 OPPS payment rates for this final rule with comment period, approximately 107 million claims were of 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 107 million claims, approximately 49 million 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 58 million claims, we created approximately 99 million single records, of which approximately 67 million were ''pseudo'' single claims (created from 26 million multiple procedure claims using the process we discuss later in this section). Approximately 617,000 claims trimmed out on cost or units in excess of +/−3 standard deviations from the geometric mean, yielding approximately 99 million single bills for median setting. This number of ''pseudo'' and ''natural'' single bills is comparable to the 97 million single bills that we used in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66589). In prior rules, we have reported the percentage of claims that we were able to use to estimate APC median costs. However, our refinement to the bypass process to accommodate the multiple imaging composite methodology described in section II.A.2.e.(5) of this final rule with comment period currently prevents us from providing an accurate percentage. Because our refinement increased the number of ''pseudo'' single bills, we are confident that we are using a high percentage of claims to estimate the final CY 2009 APC median costs. We provide greater detail on this refinement in our claims accounting narrative for this final rule with comment period that is posted on the CMS Web site.

As proposed, the APC relative weights and payments for CY 2009 in Addenda A and B to this final rule with comment period were calculated using claims from CY 2007 that were processed on or before June 30, 2008, 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 which we proposed to convert to relative payment weights for purposes of calculating the CY 2009 payment rates.

We did not receive any public comments on our proposal to base the CY 2009 APC relative weights on the most currently available cost reports and on claims for services furnished in CY 2007. Therefore, for this reason and the reasons noted above in this section, we are finalizing our data source for the recalibration of the CY 2009 APC relative payment weights as proposed, without modification, as described in this section of this final rule with comment period.

b. Use of Single and Multiple Procedure Claims

For CY 2009, in general, we proposed 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 (73 FR 41423). 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 appropriate when one and only one procedure is furnished and because we are, so far, 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 claims from claims that, as submitted, 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 claims because they were submitted by providers as multiple procedure claims. The history of our use of a bypass list to generate ''pseudo'' single claims is well documented, most recently in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66590 through 66597). In addition, for CY 2008, we increased packaging and created the first composite APCs, which also increased the number of bills 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. We refer readers to section II.A.2.e. of this final rule with comment period for discussion of the use of claims to establish median costs for composite APCs.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41423), we proposed to continue to apply these processes to enable us to use as much claims data as possible for ratesetting for the CY 2009 OPPS. This process enabled us to create, for this final rule with comment period, approximately 67 million ''pseudo'' single claims, including multiple imaging composite ''single session'' bills (we refer readers to section II.A.2.e.(5) of this final rule with comment period for further discussion), and approximately 32 million ''natural'' single bills. For this final rule with comment period, ''pseudo'' single procedure bills represent 68 percent of all single bills used to calculate median costs.

In the CY 2009 OPPS/ASC proposed rule (73FR 41424 through 41429), we proposed to bypass 452 HCPCS codes for CY 2009 that were identified in Table 1 of the proposed rule. We proposed to continue the use of the codes on the CY 2008 OPPS bypass list. 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 in each ''natural'' single bill for each code. We have generally retained the codes on the previous year's bypass list and used the update year's data (for CY 2009, data available for the first CY 2008 APC Panel meeting for services furnished on and after January 1, 2007 through and including September 30, 2007) to determine whether it would be appropriate to add additional codes to the previous year's bypass list. The entire list (including the codes that remained on the bypass list from prior years) was open to public comment. We removed two HCPCS codes from the CY 2008 bypass list for the CY 2009 proposal because the codes were deleted on December 31, 2005, specifically C8951 (Intravenous infusion for therapy/diagnosis; each additional hour (List separately in addition to C8950)) and C8955 (Chemotherapy

administration, intravenous; infusion technique, each additional hour (List separately in addition to C8954)). We updated HCPCS codes on the CY 2008 bypass list that were mapped to new HCPCS codes for CY 2009 ratesetting. We proposed to add to the bypass list all HCPCS codes not on the CY 2008 bypass list that, using the APC Panel data, met the same previously established empirical criteria for the bypass list that are summarized below. We assumed that the representation of packaging in the single claims for any given code was comparable to packaging for that code in the multiple claims. The proposed criteria for the bypass list were:

- There are 100 or more single claims for the code. This number of single claims ensures that observed outcomes are sufficiently representative of packaging that might occur in the multiple claims.
- Five percent or fewer of the single claims for the code have packaged costs on that single claim for the code. This criterion results in limiting the amount of packaging being redistributed to the separately payable procedure 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 single claims is equal to or less than $50. This limits the amount of error in redistributed costs.
- The code is not a code for an unlisted service.

In addition, we proposed to continue to include on the bypass list HCPCS codes that CMS medical advisors believe have minimal associated packaging based on their clinical assessment of the complete CY 2009 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 services they requested be added to the bypass list. To ensure clinical consistency in our treatment of related services, we also proposed to add the other CPT add-on codes for drug administration services to the CY 2009 bypass list, in addition to the CPT codes for additional hours of infusion that were previously included on the CY 2008 bypass list, because adding them enabled us to use many correctly coded claims for initial drug administration services that would otherwise not be available for ratesetting. The result of this proposal was that the packaged costs associated with add-on drug administration services were packaged into payment for the initial administration service, as has been our payment policy for the past 2 years for the CPT codes for additional hours of infusion.

We also proposed to add HCPCS code G0390 (Trauma response team activation associated with hospital critical care service) because we thought it was appropriate to attribute all of the packaged costs that appear on a claim with HCPCS code G0390 and CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) to CPT code 99291. If we had not added HCPCS code G0390 to the bypass list, we would have had many fewer claims to use to set the median costs for APCs 0617 (Critical Care) and 0618 (Trauma Response with Critical Care). By definition, we could not have had any properly coded ''natural'' single bills for HCPCS code G0390. Including HCPCS code G0390 on the bypass list allowed us to create more ''pseudo'' single bills for CPT code 99291 and HCPCS code G0390, and, therefore, to improve the accuracy of the median costs of APCs 0617 and 0618 to which the two codes were assigned, respectively. The Integrated Outpatient Code Editor (I/OCE) logic rejects a line for HCPCS code G0390 if CPT code 99291 is not also reported on the claim. Therefore, we could not assess whether HCPCS code G0390 would meet the empirical criteria for inclusion on the bypass list because we had no ''natural'' single claims for HCPCS code G0390.

As a result of the multiple imaging composite APCs that we proposed to establish for CY 2009 as discussed in section II.A.2.e.(5) of this final rule with comment period, we noted that the ''pseudo'' single converter logic for bypassed codes that are also members of multiple imaging composite APCs would change. When creating the set of ''pseudo'' single claims, claims that contain ''overlap bypass codes,'' that is, 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'' 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 single unit occurrences of these codes are identified as single bills at the end of the ''pseudo'' single processing logic. For this final rule with comment period, we then 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 claims. (We refer readers to section II.A.2.c. of this final rule with comment period for further discussion of the treatment of ''overlap bypass codes.'') This process also created multiple imaging composite ''single session'' bills that could be used for calculating composite APC median costs. ''Overlap bypass codes'' that would be members of the proposed multiple imaging composite APCs were identified by asterisks (*) in Table 1 of the CY 2009 OPPS/ASC proposed rule.

Table 1 published in the CY 2009 OPPS/ASC proposed rule included the proposed list of bypass codes for CY 2009. As noted in that proposed rule (73 FR 41424 through 41429), that list contained bypass codes that were appropriate to claims for services in CY 2007 and, therefore, included codes that were deleted for CY 2008. Moreover, there were codes on the proposed bypass list that were new for CY 2008 and which we indicated were appropriate additions to the bypass list in preparation for use of the CY 2008 claims for creation of the CY 2010 OPPS. We specifically requested public comment on the proposed CY 2009 bypass list.

Comment: Several commenters indicated that review of the CY 2007 claims data on which the CY 2009 proposed OPPS was based revealed that fewer than 10 percent of the billed lines for radiation oncology guidance codes were used in setting the proposed CY 2009 OPPS payment rates. They also asserted that more than a third of the billed lines for Image Guided Radiation Therapy (IGRT) services were being packaged into the single bills for services that are totally unrelated to radiation oncology services, such as clinic visits. They believed that this misassignment may have occurred in part as a result of the inclusion of radiation oncology services on the bypass list.

Response: We examined the combinations of codes that occurred on claims that contained guidance codes for radiation oncology services, specifically CPT codes 76950 (Ultrasonic guidance for placement of radiation therapy fields); 76965 (Ultrasonic guidance for interstitial radioelement application); 77014 (Computed tomography guidance for placement of radiation therapy fields); 77417 (Therapeutic radiology port film(s)); and 77421 (Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy), in our proposed rule data. We found that, on some claims, the costs of

image guidance for radiation therapy services were being packaged into the costs of other services such as visits, or were not available to be correctly packaged. Therefore, those costs were not being appropriately packaged into the radiation oncology services to which they were incidental and supportive.

Our analysis indicated that the inclusion of radiation oncology codes that failed to meet the empirical criteria for inclusion of the codes on the bypass list was the most likely source of the problem. We were unable to ensure that the radiation oncology codes that failed the empirical criteria could be retained on the bypass list with confidence that they would not result in incorrect or missing packaging for guidance services. We therefore removed from the proposed CY 2009 bypass list all codes in the radiation oncology series of CPT, specifically ranging from CPT code 77261 (Therapeutic radiology treatment planning; simple) through and including CPT code 77799 (Unlisted procedure, clinical brachytherapy), that did not meet the empirical criteria for inclusion on the bypass list based on CY 2009 proposed rule data. We had added many of these codes to the bypass list after reviewing and accepting the recommendations of several commenters to past OPPS proposed rules who believed that the codes were appropriate for inclusion on the bypass list (71 FR 67970 and 72 FR 66591), although they failed to meet the empirical criteria for inclusion on the bypass list.

Removing these codes from the bypass list for the CY 2009 OPPS resulted in a reduction of approximately 1 million ''pseudo'' single procedure claims but we believe that it resulted in more appropriate assignment of packaged costs. In some cases, the removal of these codes from the bypass list increased the median costs of APCs to which radiation oncology services are assigned (for example, APC 0412 (IMRT Treatment Delivery) and APC 0304 (Level I Therapeutic Radiation Treatment Preparation)) and in other cases it reduced the ''pseudo'' single bills that were available to be used to set median costs and led to decreases in medians that were calculated using the smaller set of single procedure claims (for example, APC 8001 (LDR Prostate Brachytherapy Composite)).

On balance, we believe that removing these codes from the bypass list is the most appropriate approach for this final rule with comment period to ensure that packaged costs are correctly captured in ratesetting. Although we have removed all codes in the radiation oncology series that do not meet the empirical criteria for inclusion on the bypass list for this CY 2009 final rule with public comment period, we will continue to examine the claims data for these codes, and particularly for the APCs for which the number of usable claims declined. We hope to determine if there are specific codes in the radiation oncology series that do not meet the empirical bypass list criteria but which could be safely added back to the bypass list without resulting in inappropriate packaging, in order to enable the use of more claims data for radiation oncology services.

Comment: One commenter expressed support for the ratesetting methodology using single and ''pseudo'' single claims and recommended that CMS continue to use methodologies that improve the overall accuracy of the cost estimate calculations.

Response: We appreciate the commenter's support. We will continue to use our established methodologies and continue to evaluate additional refinements and improvements to our methodologies, with the goal of achieving appropriate and accurate estimates of the costs of services in the HOPD.

Comment: One commenter supported inclusion of HCPCS code G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesion, per session, second through fifth session, maximum) on the bypass list.

Response: We appreciate the commenter's support and have continued to include HCPCS code G0340 on the CY 2009 bypass list.

Comment: One commenter requested clarification regarding the standards by which codes are added to the bypass list, believing that CMS' proposal to include HCPCS code G0390 on the bypass list would affect the billing of the code.

Response: The purpose of the bypass list is to isolate resource costs associated with an individual service through identifying the costs of HCPCS codes with little or no packaging and using that cost data to create ''pseudo'' single claims. The remaining costs of other services on the claim are then evaluated to determine if the claim qualifies as a single bill that can be used for ratesetting. The use of empirical criteria and clinical assessment ensure that there is minimal and infrequent packaging associated with services on the bypass list, making additional ''pseudo'' single claims for the bypass services available for ratesetting and potentially making the claims with the bypass code's costs removed appropriate for ratesetting for other services on the same claim. In the case of HCPCS code G0390 and CPT code 99291, as described above, inclusion of HCPCS code G0390 on the bypass list allows us to develop more accurate estimates of the median costs of CPT code 99291 and HCPCS code G0390 than otherwise would be possible. However, the bypass list is only used for data purposes and has no effect on how hospitals report services on claims. We fully expect hospitals to continue reporting HCPCS code G0390 when a critical care visit qualifies for trauma activation, in accordance with our instructions in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 4, Section 160.1.

Comment: One commenter recommended that CPT code 90768 (Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug): Concurrent infusion (List separately in addition to code for primary procedure)) be included on the bypass list in order to ensure consistency with the treatment of other drug administration codes.

Response: We have not added CPT code 90768 to the bypass list because our CY 2009 policy unconditionally packages payment for this service and, therefore, it is not a candidate for the bypass list. The purpose of the bypass list is to develop ''pseudo'' single claims so that there are more data available to determine the median costs of separately payable services for ratesetting purposes. Including packaged codes would be contrary to the purpose of the bypass list. For further discussion of packaged payment in CY 2009 for CPT code 90768, we refer readers to section VIII.B. of this final rule with comment period.

Comment: One commenter suggested that CMS claims data for CY 2007 showed a number of guidance and radiological supervision and interpretation ''dependent'' HCPCS codes are not on claims with paid procedures in many cases, due in part to the interaction with the bypass list, and therefore, their costs are not used in ratesetting. They urged CMS to ensure that the packaging and composite methodologies are meeting the goals of capturing accurate multiple claims data.

Response: The empirical criteria through which most codes are added to the bypass list are set to limit bypass codes to those codes which seldom have packaging, and when packaging exists, ensure limited packaging associated with the code. This is to ensure that any remaining packaging left after removal of the bypass codes would be minimal

and uncommon. As discussed above in response to the comment on image guidance for radiation oncology services, we have made some changes to the final CY 2009 bypass list to remove certain radiation oncology codes from the bypass list that do not meet the empirical criteria. Those bypass list changes ensure that the packaged costs of image guidance services for radiation therapy are not lost or misdirected to payment for other unrelated services. Furthermore, we have reviewed the other guidance HCPCS codes that are unconditionally packaged under the CY 2009 OPPS, and we do not believe that there are other HCPCS codes included on the bypass list that fail to meet the empirical criteria and to which the packaged costs of these other guidance services would be appropriately assigned. Thus, we do not believe that other changes to the bypass list to appropriately capture and assign the costs of other guidance services are necessary.

With regard to the radiological supervision and interpretation HCPCS codes, these codes are conditionally packaged codes assigned status indicator ''Q2'' (''T-packaged'') to reflect that their payment would be packaged when one or more surgical procedures (status indicator ''T'') are provided on the same day, but otherwise they would be separately paid. The determination of packaged versus separately payable status is made for radiological supervision and interpretation codes prior to application of the bypass list to develop ''pseudo'' single claims. Of note, there are only 22 ''T'' status codes on the bypass list, out of a total of 424 final bypass codes, and many of the ''T'' status codes on the bypass list are minor skin treatment procedures. Most of these ''T'' status procedures currently meet the empirical criteria for inclusion on the bypass list, so we do not believe that radiological supervision and interpretation services generally appear on claims with only those ''T'' status procedures or would be appropriately packaged with those procedures. Therefore, we continue to believe that the costs of packaged radiological supervision and interpretation services are being appropriately captured for purposes of ratesetting, and those costs are not being lost or misassigned due to an interaction with the bypass list.

After consideration of the public comments received, we are adopting, as final, the proposed ''pseudo'' single claims process and the final CY 2009 bypass list of 424 HCPCS codes, as displayed in Table 1 below. This list has been modified from the CY 2009 proposed list, with the removal of certain HCPCS codes as discussed above in this section.

TABLE 1—FINAL CY 2009 BYPASS CODES FOR CREATING ''PSEUDO'' SINGLE CLAIMS FOR CALCULATING MEDIAN COSTS

HCPCS code	Short descriptor	''Overlap bypass codes''
0144T	CT heart w/o dye; qual calc.	.....
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.	.....
17003	Destruct premalg les, 2–14.	.....
29220	Strapping of low back	.....
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	.....
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.	.....
70250	X-ray exam of skull ...	.....
70260	X-ray exam of skull ...	.....
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 ..	.....
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.	*
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.	.....
72100	X-ray exam of lower spine.	.....
72110	X-ray exam of lower spine.	.....
72114	X-ray exam of lower spine.	.....

TABLE 1—FINAL CY 2009 BYPASS CODES FOR CREATING "PSEUDO" SINGLE CLAIMS FOR CALCULATING MEDIAN COSTS—Continued

HCPCS code	Short descriptor	"Overlap bypass codes"
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 ..	.....
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.	*
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.	.....
76999	Echo examination procedure.	.....
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.	.....
77301	Radiotherapy dose plan, imrt.	.....
77315	Teletx isodose plan complex.	.....
77336	Radiation physics consult.	.....
77401	Radiation treatment delivery.	.....
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.	.....

TABLE 1—FINAL CY 2009 BYPASS CODES FOR CREATING "PSEUDO" SINGLE CLAIMS FOR CALCULATING MEDIAN COSTS—Continued

HCPCS code	Short descriptor	"Overlap bypass codes"
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.	
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	
88313	Special stains	
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.	
88399	Surgical pathology procedure.	
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.	
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 add-on.	
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, w/e&m.	
90810	Intac psytx, off, 20–30 min.	
90811	Intac psytx, 20–30, 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.	
90899	Psychiatric service/therapy.	
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 ..	
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.	
92546	Sinusoidal rotational test.	
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.	

TABLE 1—FINAL CY 2009 BYPASS CODES FOR CREATING "PSEUDO" SINGLE CLAIMS FOR CALCULATING MEDIAN COSTS—Continued

HCPCS code	Short descriptor	"Overlap bypass codes"
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	.....
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.	.....
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 ..	.....

TABLE 1—FINAL CY 2009 BYPASS CODES FOR CREATING "PSEUDO" SINGLE CLAIMS FOR CALCULATING MEDIAN COSTS—Continued

HCPCS code	Short descriptor	"Overlap bypass codes"
95115	Immunotherapy, one injection.	.....
95117	Immunotherapy injections.	.....
95165	Antigen therapy services.	.....
95250	Glucose monitoring, cont.	.....
95805	Multiple sleep latency test.	.....
95806	Sleep study, unattended.	.....
95807	Sleep study, attended	.....
95808	Polysomnography, 1–3.	.....
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.	.....

TABLE 1—FINAL CY 2009 BYPASS CODES FOR CREATING "PSEUDO" SINGLE CLAIMS FOR CALCULATING MEDIAN COSTS—Continued

HCPCS code	Short descriptor	"Overlap bypass codes"
96153	Intervene hlth/behave, group.	.....
96402	Chemo hormon antineopl sq/im.	.....
96411	Chemo, iv push, addl drug.	.....
96415	Chemo, iv infusion, addl hr.	.....
96417	Chemo iv infus each addl seq.	.....
96423	Chemo ia infuse each addl hr.	.....
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.	.....
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	.....
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.	.....
G0340	Robt lin-radsurg fractx 2–5.	.....
G0344	Initial preventive exam.	.....
G0365	Vessel mapping hemo access.	.....
G0367	EKG tracing for initial prev.	.....

TABLE 1—FINAL CY 2009 BYPASS CODES FOR CREATING ''PSEUDO'' SINGLE CLAIMS FOR CALCULATING MEDIAN COSTS—Continued

HCPCS code	Short descriptor	''Overlap bypass codes''
G0376	Smoke/tobacco counseling >10.	.....
G0389	Ultrasound exam AAA screen.	.....
G0390	Trauma Respons w/ hosp criti.	.....
M0064	Visit for drug monitoring.	.....
Q0091	Obtaining screen pap smear.	.....

c. Calculation of CCRs

(1) Development of the CCRs

We calculated hospital-specific overall CCRs and hospital-specific departmental CCRs for each hospital for which we had CY 2007 claims data. For CY 2009 OPPS ratesetting, we used the set of claims processed during CY 2007. 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.hhs.gov/HospitalOutpatientPPS/03_crosswalk.asp#TopOfPage*. 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.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41429), we proposed to make a change to the revenue code-to-cost center crosswalk for the CY 2009 OPPS. Specifically, for revenue code 0904 (Activity Therapy), we proposed to make cost center 3550 (Psychiatric/Psychological Services) the primary cost center and to make cost center 6000 (Clinic services) the secondary cost center. For CY 2008, for revenue code 0904, the primary cost center is 3580 (Recreational Therapy), cost center 3550 is secondary; and cost center 6000 is tertiary. We proposed this change to conform the OPPS methodology for hospital claims to the crosswalk that is being used to calculate partial hospitalization costs for CMHCs.

We would like to affirm that the longstanding Medicare principles of cost apportionment at § 413.53 convey that, under the departmental method of apportionment, the cost of each ancillary department is to be apportioned separately rather than being combined with another department. However, CMS does not specify a revenue code-to-cost center crosswalk that hospitals must adopt to prepare the cost report, but instead, requires hospitals to submit their individual crosswalk to the Medicare contractor when the cost report is filed. The proposed CY 2009 OPPS revenue code-to-cost center crosswalk contains several potential cost center locations for a revenue code because it is an attempt to best represent the association of revenue codes with cost centers across all hospitals for modeling purposes. Assignment to cost centers is mutually exclusive and only defaults to the next level when the cost center with higher priority is unavailable. The changes to the crosswalk for revenue code 0904 mentioned above are used by CMS for modeling purposes only, and we fully expect hospitals to comply with the Medicare reimbursement policies when reporting their costs and charges in the cost report.

At the August 2008 APC Panel meeting, we reviewed with the APC Panel's Data Subcommittee the current revenue code-to-cost center crosswalk, as well as other data in preparation for the CY 2009 rulemaking cycle. At this meeting, the APC Panel recommended that the Data Subcommittee continue its work and we are accepting that recommendation. We will continue to work with the APC Panels' Data Subcommittee to prepare and review data and analyses relevant to the APC configurations and OPPS payment policies for hospital outpatient items and services.

We received no public comments on this proposal and, therefore, we are finalizing our proposal for CY 2009, without modification, to calculate hospital-specific overall and departmental CCRs as described above in this section.

(2) Charge Compression

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 incorporate 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. Commenters expressed increased concern about the impact of charge compression when CMS began setting the relative weights for payment under the IPPS based on the costs of inpatient hospital services, rather than the charges for the services.

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 relative weights, particularly with regard to the impact on inpatient diagnosis-related group (DRG) payments, and to consider methods to capture better the variation in cost and charges for individual services when calculating costs for the IPPS relative weights across services in the same cost center. Of specific note was RTI's analysis of a regression-based methodology estimating an average adjustment for CCR by type of revenue code from an observed relationship between provider cost center CCRs and proportional billing of high and low cost services in the revenue codes associated with the cost center in the claims data. RTI issued a report in March 2007 with its findings on charge compression. The report is available on the CMS Web site at: *http://www.cms.hhs.gov/reports/downloads/Dalton.pdf.* Although this report was focused largely on charge compression in the context of the IPPS cost-based relative weights, several of the findings were relevant to the OPPS. Therefore, we discussed the findings and our responses to that interim draft 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).

We did not propose any changes to address charge compression for CY 2008. RTI noted in its 2007 report that its research was limited to IPPS DRG cost-based weights and that it did not examine potential areas of charge compression specific to hospital outpatient services. We were concerned that the analysis was too limited in scope because typically hospital cost report CCRs encompass both inpatient and outpatient services for each cost center. Further, because both the IPPS and OPPS rely on cost-based weights, we preferred to introduce any methodological adjustments to both payment systems at the same time. We believe that because charge compression affects the cost estimates for services paid under both IPPS and OPPS in the same way, it is appropriate that we would use the same or, at least, similar approaches to address the issue. Finally, we noted that we wished to assess the

educational activities being undertaken by the hospital community to improve cost reporting accuracy in response to RTI's findings, either as an adjunct to or in lieu of regression-based adjustments to CCRs.

We have since expanded RTI's analysis of charge compression to incorporate outpatient services. In August 2007, we again contracted with RTI. Under this contract, we asked RTI to evaluate the cost estimation process for the OPPS relative weights. This research included a reassessment of the regression-based CCR models using hospital outpatient and inpatient charge data, as well as a detailed review of the OPPS revenue code-to-cost center crosswalk and the OPPS' hospital-specific CCR methodology. In evaluating cost-based estimation, in general, the results of RTI's analyses impact both the OPPS APC relative weights and the IPPS MS–DRG (Medicare-Severity) relative weights. With the release of the IPPS FY 2009 proposed rule in April 2008, CMS posted an interim report discussing RTI's research findings for the IPPS MS–DRG relative weights to be available during the public comment period on the FY 2009 IPPS proposed rule. This 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_200804.pdf*. The IPPS-specific chapters, which were separately displayed in the April 2008 interim report, as well as the more recent OPPS chapters, are included in the July 2008 RTI final report entitled, ''Refining Cost to Charge Ratios for Calculating APC and DRG Relative Payment Weights,'' which became available at the time of the publication of the CY 2009 OPPS/ASC proposed rule. 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*.

RTI's final report distinguished between two types of research findings and recommendations, those pertaining to the accounting or cost report data itself and those related to statistical regression analysis. Because the OPPS uses a hospital-specific CCR methodology, employs detailed cost report data, and estimates costs at the claim level, CMS asked RTI to closely evaluate the accounting component of the cost-based weight methodology, specifically the revenue code-to-cost center crosswalk. In reviewing the cost report data for nonstandard cost centers used in the crosswalk, RTI discovered some problems concerning the classification of nonstandard cost centers and reclassified nonstandard cost centers by reading providers' cost center labels. Standard cost centers are preprinted in the CMS-approved cost report software and constitute the minimum set of cost centers that must be reported on the Medicare hospital cost report if a hospital includes that cost center in its own internal accounts. Nonstandard cost centers are additional common cost centers available to hospitals for reporting when preparing their Medicare hospital cost report. To the extent hospitals provide services captured by nonstandard cost centers, they should report the relevant nonstandard cost centers as well, if the service is captured in a separate account and qualifies as a cost center in accordance with the Provider Reimbursement Manual (PRM)–I, Section 2302.8. RTI also evaluated the revenue code-to-cost center crosswalk after examining hospitals' cost report and revenue code billing patterns in order to reduce aggregation bias inherent in defaulting to the overall ancillary CCR and generally to improve the empirical accuracy of the crosswalk.

With regard to the statistical adjustments, RTI confirmed the findings of its March 2007 report that regression models are a valid approach for diagnosing potential aggregation bias within selected services for the IPPS and found that regression models are equally valid for setting payments under the OPPS. RTI also suggested that regression-based CCRs could provide a short-term correction for charge compression until accounting data could be refined to support more accurate CCR estimates under both the IPPS and the OPPS. RTI again found aggregation bias in devices, drugs, and radiology and, using combined outpatient and inpatient claims, expanded the number of recommended regression-adjusted CCRs.

In almost all cases, RTI observed that potential distortions in the APC relative weights were proportionally much greater than for MS–DRGs for both accounting-based and statistical adjustments because APC groups are small and generally price a single service. However, just as the overall impacts on MS–DRGs were more moderate because MS–DRGs experienced offsetting effects of changes in cost estimation, a given hospital outpatient visit might include more than one service, leading to offsetting effects in cost estimation for services provided in the outpatient episode as a whole. In general, APC relative weights are more volatile than MS–DRG relative weights from year to year yet OPPS provider impacts are typically quite modest and, in light of this experience, we expect that overall provider impacts could be much more moderate than those suggested by individual APC impacts from the RTI analysis.

Notwithstanding likely offsetting effects at the provider level, RTI asserted that, while some averaging is appropriate for a prospective payment system, extreme distortions in APC payments for individual services bias perceptions of service profitability and may lead hospitals to inappropriately set their charge structure. RTI noted that this may not be true for ''core'' hospital services, such as oncology, but these distortions may have a greater impact in evolving areas with greater potential for provider-induced demand, such as specialized imaging services. RTI also noted that cost-based weights are only one component of a final prospective payment rate. There are other rate adjustments (wage index, indirect medical education (IME), and disproportionate share hospital (DSH)) to payment derived from the revised cost-based weights and the cumulative effect of these components may not improve the ability of final payment to reflect resource cost. With regard to APCs and MS–DRGs that contain substantial device costs, RTI cautioned that other prospective payment system adjustments (wage index, IME, and DSH) largely offset the effects of charge compression among hospitals that receive these adjustments. Although RTI endorsed short-term regression-based adjustments, RTI also concluded that more refined and accurate accounting data are the preferred long-term solution to mitigate charge compression and related bias in hospital cost-based weights.

As a result of this research, RTI made 11 recommendations, 2 of which are specific to IPPS MS–DRGs and were not discussed in the CY 2009 OPPS/ASC proposed rule, nor are they discussed in this final rule with comment. The first set of non-IPPS-specific recommendations concentrates on short-term accounting changes to current cost report data; the second set addresses short-term regression-based and other statistical adjustments. RTI concluded its recommendations with longer-term accounting changes to the cost report. (RTI report, ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights,'' July 2008.) Given the magnitude and scope of impacts on APC relative weights that would result from adopting both accounting and statistical changes, as specifically observed in Chapter 6 of RTI's July 2008 final report and Attachments 4a, 4b, and 5 (RTI report, ''Refining Cost to Charge Ratios for

Calculating APC and MS–DRG Relative Payment Weights,'' July 2008), we did not propose to adopt any short-term adjustments to OPPS payment rate calculations for CY 2009 (73 FR 41430 through 41431). Furthermore, the numerous and substantial changes that RTI recommended have significantly complex interactions with one another and we believe that we should proceed cautiously. In a budget neutral payment system, increases in payment for some services must be countered by reductions to payment for other services.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41431), we did not propose to adopt, but specifically requested general public comments on, several of RTI's recommended accounting-based changes pertaining to the cost report as discussed below because we plan to consider the public comments in our current revision of the Medicare hospital cost report and for CY 2010 OPPS ratesetting. We believe that improved and more precise cost reporting is the best way to improve the accuracy of all cost-based payment weights, including relative weights for the IPPS MS–DRGs. Because both the IPPS and the OPPS rely on cost-based weights derived, in part, from data on the Medicare hospital cost report form, we indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41431) that the requested public comments on recommended changes to the cost report should address any impact on both the inpatient and outpatient payment systems.

We noted in the FY 2009 IPPS final rule (73 FR 48467 through 48468), that we are updating the cost report form to eliminate outdated requirements in conjunction with the Paperwork Reduction Act (PRA), and that we plan to propose actual changes to the cost reporting form, the attending cost reporting software, and the cost report instructions in Chapter 36 of the PRM–II. We indicated that we now believe the revised cost report may not be available until cost reporting periods starting after the Spring of 2009. Because there is generally a 3-year lag between the availability of cost report data for IPPS and OPPS ratesetting purposes in a given calendar year, we may be able to use data from the revised cost report form for CY 2012 or CY 2013 OPPS relative weights.

In the FY 2009 IPPS final rule, we finalized our proposal for both OPPS and IPPS to add one cost center to the cost report so that, in general, the costs and charges for relatively inexpensive medical supplies would be reported separately from the costs and charges for more expensive implantable devices (such as pacemakers and other implantable devices). Specifically we will create one cost center for ''Medical Supplies Charged to Patients'' and one cost center for ''Implantable Devices Charged to Patients.'' This change ultimately will split the current CCR for Medical Supplies and Equipment into one CCR for medical supplies and another CCR for implantable devices. In response to support from a majority of commenters on the FY 2009 IPPS proposed rule, we finalized a definition of the Implantable Devices Charged to Patients cost center as capturing the costs and charges billed with the following UB–04 revenue codes: 0275 (Pacemaker), 0276 (Intraocular lens), 0278 (Other implants), and 0624 (FDA investigational devices). Identifying most implantable devices based on the existing revenue code definitions is the most straightforward and easiest means of capturing device costs, although some charge compression will remain in the resulting device and supply CCRs. Hospitals are already familiar with National Uniform Billing Committee (NUBC) billing instructions, and we believe this definition will minimize the disruption to hospitals' accounting and billing systems. For a complete discussion of the proposal, public comments, and our responses, we refer readers to section II.E.4. of the FY 2009 IPPS final rule (73 FR 48458 through 45467).

RTI's first set of recommendations for accounting changes addressed improved use of existing cost report and claims data. RTI recommended: (1) Immediately using text searches of providers' line descriptions to identify provider-specific cost centers and ultimately to more appropriately classify nonstandard cost centers in current hospital cost report data; (2) changing cost report preparation software to impose fixed descriptions on nonstandard cost centers; (3) slightly revising CMS' cost center aggregation table to eliminate duplicative or misplaced nonstandard cost centers and to add nonstandard cost centers for common services without one; and (4) adopting RTI's recommended changes to the revenue code-to-cost center crosswalk.

Given the magnitude and scope of impacts resulting from RTI's recommended revisions, we did not propose to adopt any of the short-term accounting changes, including text searches of providers' line descriptions to more appropriately classify nonstandard cost centers and changes to the revenue code-to-cost center crosswalk. As indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41431), we stated that we would modify the cost report preparation software. This revision will print a brief fixed description next to each nonstandard cost center number, while continuing to allow the hospital to enter a description, and will be incorporated in the 2009 Medicare hospital cost report preparation software.

With regard to revisions to the cost center aggregation table, we specifically invited public comment on whether several identified cost centers are duplicative (RTI report, ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights,'' July 2008). We also specifically requested public comment on creation of new nonstandard cost centers for services that are well represented in line descriptions reported with ''other ancillary services'' and other outpatient nonstandard cost centers, but for which no specific nonstandard cost center currently exists and for which UB–04 revenue codes do exist, including cardiac rehabilitation, hyperbaric oxygen therapy, and patient education (RTI report, ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights,'' July 2008) (73 FR 41431).

Comment: Many commenters expressed support for refining the Healthcare Cost Report Information System (HCRIS) database that CMS uses for ratesetting by using text string searches to reassign cost center lines based on the description entered by the hospital, in order to mitigate hospital error in assigning a nonstandard HCRIS cost center code. Commenters viewed this change as a way to improve the accuracy of the CCRs derived from the cost report for cost estimation, without imposing additional burden on hospitals. Many commenters also supported CMS' modification to add fixed descriptions to nonstandard cost center lines in the cost reporting software, with the caveat that hospitals continue to be allowed to enter their own nonstandard cost center descriptions. The commenters believed that this change would improve the quality and consistency of hospital reporting. One commenter indicated that CMS should clarify instructions about the specific cost centers that should be reported on nonstandard lines. Another commenter noted that a cost center for patient education could be difficult to report because patient education can take place across multiple departments and reclassifying costs could be challenging. Many commenters supported RTI's recommendation to modify the cost aggregation table to

eliminate duplicative or misplaced nonstandard cost centers but emphasized that hospitals should not be required to report the revised cost centers. A number of commenters supported the addition of nonstandard cost centers that also have a UB–04 revenue code, including Cardiac Rehabilitation, Patient Education, Hyperbaric Oxygen Therapy, and Lithotripsy.

Response: With regard to modifying the cost reporting preparation software to impose fixed descriptions for nonstandard cost centers, we stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41431) that we would make this change in the cost reporting preparation software accompanying the revised Medicare hospital cost report form. Should release of the revised form be delayed, we will make this change for the next release of the cost report preparation software. Hospitals will continue to be able to enter their own description of the nonstandard cost center. This modification will act as a quality check for hospitals to review their choice of nonstandard cost center code and encourage hospitals to more accurately report their nonstandard cost centers without significantly increasing provider burden.

We appreciate the commenters' argument that text string searches could refine submitted cost report data without imposing hospital burden. However, we will not implement RTI's recommended text string search algorithm for CY 2009 because it would introduce significant changes in APC median costs in concentrated areas with significant Medicare charges and utilization and because it would represent a major shift in the current way we use cost report data. Our preference in the median cost development process has been to accept the information submitted by hospitals as it is received, only trimming egregiously erroneous data through conservative statistical methods in order to maintain the integrity of the original data set. Modifying the data from its submitted form based on assumptions about the data typically would be contrary to our principle of using the data as submitted by hospitals. Further, implementing an algorithm that reassigns nonstandard cost center lines based on their HCRIS descriptions would entail assumptions about what that hospital's written description means and what the data represent. For example, RTI reassigned cost center lines with combined descriptions, such as ''Radiation and Oncology,'' to the cost center with the highest dollar volume, in this case Radiation Therapy. However, we are not confident that the assumptions underlying these reassignments are correct. We will continue to examine the quality of the data submitted by hospitals and may consider implementing the text string searches in the future.

While many commenters expressed general support for RTI's recommendation to eliminate duplicative nonstandard cost centers with low volume from the cost aggregation table, we continue to consider whether we should retain these cost centers. We note that RTI's analysis only included an examination of the nonstandard cost centers from more recent cost reports. Observing data from older cost reports may have led RTI to conclude that the same nonstandard cost centers would nonetheless be necessary. For continuity with historical cost report data, at this time we do not plan to eliminate any duplicative nonstandard cost centers from the cost center aggregation table.

As part of its recommendation for modifications to the cost aggregation table, RTI suggested adding new nonstandard cost centers for hospital departments that were well represented in the cost report data and had an associated UB–04 revenue code but lacked their own nonstandard cost center, specifically Cardiac Rehabilitation, Patient Education, Hyperbaric Oxygen Therapy, and Lithotripsy. Many commenters were supportive of these changes, believing that these cost centers would result in more accurate cost estimates for the services in question, but they were concerned about additional burden associated with reporting new cost centers. One commenter indicated that reporting patient education could be difficult.

We do not expect additional burden for reporting these new nonstandard cost centers to be significant because hospitals that provide these services and maintain a separate account for each of these services in their internal accounting records to capture the costs and charges are currently required, in accordance with § 413.53(a)(1), to report these cost centers in the cost report, even if CMS does not identify a nonstandard cost center code for the department(s). Specifically, under those regulations defining the departmental method of cost apportionment, the hospital must separately apportion the costs of each ancillary department. CMS defines a cost center in PRM–I, Section 2302.8, as an organizational unit, generally a department or its subunit, having a common functional purpose for which direct and indirect costs are accumulated, allocated, and apportioned. Hospitals that do not maintain distinct departments or accounts in their internal accounting systems for Cardiac Rehabilitation, Hyperbaric Oxygen Therapy, or Lithotripsy would not be required to report these nonstandard cost centers. We plan to include nonstandard cost center codes for Cardiac Rehabilitation, Hyperbaric Oxygen Therapy, and Lithotripsy on the revised Medicare hospital cost report form that we provide to the public for comment through the PRA process, because we believe these changes will facilitate more accurate cost reporting for these services.

With regard to ''patient education,'' we agree with the commenter that ''education'' may not be sufficiently definitive to serve as a useful cost center. We will review RTI's findings on the presence of patient education in the HCRIS data to see if we should narrow the scope of this label to improve its usefulness as a nonstandard cost center. Based on this review, we may include a nonstandard cost center like Patient Education on the revised Medicare hospital cost report form that we provide for public comment through the PRA process.

In summary, CMS continues to examine ways in which it can improve the cost reporting process. We have already implemented the minor change in the cost reporting software by imposing fixed descriptions on nonstandard cost centers. We also plan to add the new nonstandard cost centers for Cardiac Rehabilitation, Hyperbaric Oxygen Therapy, and Lithotripsy, as well as potentially a nonstandard cost center like Patient Education, to the nonstandard list when we revise the Medicare hospital cost report form. We will consider the appropriateness of the text string searches for future ratesetting.

Comment: One commenter requested that CMS issue a detailed written explanation of CMS's processes for collecting, reviewing, and aggregating data, and reviewing and adjusting cost data to arrive at median cost amounts, specifically in the context of hyperbaric oxygen therapy services.

Response: This final rule with comment period contains a comprehensive discussion of the process through which we use cost report and claims data to arrive at median costs in sections II.A.1. and II.A.2. The claims accounting narrative mentioned earlier, available on the CMS Web site, offers a detailed breakdown of the processing logic CMS uses to refine the claims data set, as well as exact

counts of claims involved in each stage of that process.

CMS also requested comment in the CY 2009 OPPS/ASC proposed rule (73 FR 41431) on RTI's recommended changes to the OPPS revenue code-to-cost center crosswalk. We indicated that we may propose to adopt crosswalk changes for CY 2010 based on RTI's analyses and related public comments received on this issue. Although available on the CMS Web site for continuous public comment, we have received relatively few public comments over the last several years on the OPPS revenue code-to-cost center crosswalk, which has undergone only minimal change since the inception of the OPPS. RTI's revised crosswalk in Attachment 2b of its final report reflected all accounting changes, including reclassification of nonstandard cost centers from text searches, removal of duplicative cost centers, and addition of new nonstandard cost centers for common services (RTI report, ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights,'' July 2008). Throughout the July 2008 final report, RTI used a subscripting nomenclature developed from CMS's aggregation table to identify cost centers. To disentangle the combined impact of these changes and clearly communicate RTI's recommended changes in current HCRIS cost center numbers, we made available on the CMS Web site a revised (RTI-recommended) crosswalk using current standard and nonstandard cost centers codes in the same format as the crosswalk proposed for the CY 2009 OPPS. This revised (RTI-recommended) crosswalk may be found on the CMS Web site under supporting documentation for this final rule with comment period at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/list.asp#TopOfPage*. We did not include RTI's recommended new nonstandard cost centers in this revised crosswalk as they are not yet active.

We specifically requested public comment on the numerous changes included in this crosswalk (73 FR 41431). We were interested in public opinion about the addition of ''default'' CCRs for clinic, cardiology, and therapy services before defaulting to the overall ancillary CCR, as is our current policy. The overall ancillary CCR, which is the traditional default CCR, is charge-weighted and heavily influenced by the relationship between costs and charges for surgical and imaging services. RTI also introduced cost center 4300 (Radioisotope) as a primary cost converter for the nuclear medicine revenue codes (034X). Further, RTI added secondary and tertiary crosswalk maps for services that frequently appear together, such as CCRs for Computed Tomography (CT) Scan as a secondary cost converter for the Magnetic Resonance Imaging (MRI) revenue codes (061X) (RTI report, ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights,'' July 2008).

Comment: Some commenters supported full adoption of the RTI-recommended revenue code-to-cost center crosswalk, which included expanded and revised crosswalks. Others believed that they could not comment on the proposal, including the addition of default CCRs for cardiology, therapy, and clinic services, until CMS provides additional information comparing the cost-based weights under the current and RTI-recommended crosswalks that would illustrate the impact of these changes. Other commenters wondered whether the crosswalk would be applied under both the IPPS for estimating DRG relative weights and the OPPS for estimating APC relative weights.

One commenter requested that CMS update the revenue code-to-cost center crosswalk to reflect the cost report change finalized in the FY 2009 IPPS final rule to create a new implantable device cost center. Some commenters expressed support for using cost center 4300 (Radioisotope) as a primary cost converter for the nuclear medicine revenue code series 0340 to 0349, which includes revenue codes for nuclear medicine and radiopharmaceuticals. One commenter believed that cost center 2500 (Adults and Pediatrics (General Routine Care)) offered the appropriate CCR for estimating costs from charges on revenue code 0762 (Observation Room), instead of cost center 6200 (Observation Beds). Another commenter recommended removing cost center 3540 (Prosthetic Devices) as the primary CCR for revenue code 0275 (Pacemaker) and only keeping cost center 5500 (Medical Supplies Charged to Patients) in the crosswalk. The same commenter pointed out that hospitals frequently bill certain imaging services under revenue code 0361 (Operating Room Services: Minor Surgery) because of billing requirements by Medicare Administrative Contractors (MACs) and non-Medicare payers. This practice ensures that a radiology CCR would not be used to estimate costs for these radiology services under the OPPS cost methodology.

Response: The RTI-recommended revenue code-to-cost center crosswalk included significant changes from the current OPPS crosswalk that would impact the APC relative payment weights considerably. While several of RTI's recommendations to improve CMS' processes for estimating costs from charges would apply to both the IPPS and the OPPS, the revenue code-to-cost center crosswalk is specific to the OPPS. We agree with the commenters that observing the actual median costs associated with the revised crosswalk would help to inform public comment. We note that the majority of the changes detailed under the (RTI_1) column in Attachment 4a of RTI's final report are attributable to the revised crosswalk (RTI report, ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights,'' July 2008). Like many commenters, we also believe that RTI's recommended changes are improvements. For example, we expect that default CCRs for clinic services, cardiology, and therapy that are specific to those types of services would be appropriate for more accurately estimating cost when the hospital has not reported a clinic, cardiology, or therapy cost center. However, we understand that commenters may not have been able to fully absorb the changes discussed in RTI's report and would benefit from a streamlined comparison of median costs that isolates changes attributable to the revenue code-to-cost center crosswalk.

We did not receive many detailed comments about specific revenue code and cost center relationships in the crosswalk, and we will therefore not adopt significant changes to the crosswalk until we provide such a comparison. Informed analysis and public comment regarding the RTI-recommended changes to the revenue code-to-cost center crosswalk would help to ensure that any final changes would be appropriate and likely to result in more accurate data. We will update the revenue code-to-cost center crosswalk when the new device cost centers and new nonstandard cost centers are included in the Medicare hospital cost report form and corresponding HCRIS database.

We appreciate the small number of commenters who provided thoughtful input on specific adjustments to the revenue code-to-cost center crosswalk. We will consider these and any further public comments regarding RTI's recommended revisions to the revenue code-to-cost center crosswalk as we consider crosswalk revisions for future OPPS updates. We are not adopting RTI's revised revenue code-to-cost center crosswalk for the CY 2009 OPPS. Furthermore, we intend to explore

differences between revenue code billing requirements set by contractors and NUBC revenue code definitions.

RTI's second set of recommendations concentrated on short-term statistical regression-based adjustments to address aggregation bias. RTI recommended: (1) Adopting regression-adjusted OPPS CCRs for Devices, Other Supplies Sold, Additional Detail Coded Drugs, and Intravenous (IV) Solutions and Other Drugs Sold; and (2) adopting a set of CCRs that blend corrected cost report and regression-adjusted CCRs for CT scanning, MRI, therapeutic radiology, nuclear medicine, and other diagnostic radiology services for hospitals that did not report these standard and nonstandard cost centers. We agree that improved data for cost estimation in these areas is a desirable goal. However, we historically have received mixed support for regression-adjusted CCRS through both the IPPS and OPPS regulatory process. For this reason, we have chosen to concentrate our efforts on concrete steps to improve the quality of cost report accounting data that ultimately would be used to calculate both hospital inpatient and outpatient prospective payment system relative weights. We specifically did not propose to adopt regression-adjusted CCRs for the CY 2009 OPPS. In the FY 2009 IPPS final rule (73 FR 48457), we emphasized our fundamental goal of improving cost report accounting data through revisions to the cost report and our support of education initiatives, rather than introducing short-term statistical adjustments.

Comment: Many commenters expressed general support for all of RTI's recommended regression-adjusted CCRs to improve the overall accuracy of the OPPS relative weights. One commenter specifically noted that CMS should not delay applying regression-based adjustments to CCRs for APC payment calculations because the agency chose not to implement regression-adjusted CCRs for FY 2009 IPPS payments. Some commenters supported the CMS' decision not to implement the short-term statistical adjustments recommended by RTI. A number of commenters believed that actual hospital data should be used for ratesetting to ensure accuracy in payment rates. Other commenters did not support the adoption of regression-adjusted CCRs until CMS could provide enough information to show the payment impact and redistribution of costs. A few commenters noted that CMS should actually propose specific refinements and discuss the methodology behind such a proposal. Many commenters requested that CMS proceed with caution with regard to making any changes that could significantly affect the payment system.

Numerous commenters expressed support for the use of regression-adjusted CCRs for devices in order to improve short-term accuracy in the OPPS relative payment weights by addressing charge compression arising from use of a single CCR for supplies and devices. These commenters viewed regression-adjusted CCRs as a suitable temporary adjustment for charge compression until CCRs for the new Implantable Devices Charged to Patients cost center, finalized in the FY 2009 IPPS final rule (73 FR 48458 through 48469), become available in CY 2012 or CY 2013. Many commenters saw regression-adjusted CCRs for devices as a necessary solution that would be immediately available and appropriate, especially because they believed that other options, such as provider education, could not address the issue of highly variable markup rates compressed by a single CCR during cost estimation. Those commenters offered varied suggestions for implementing regression-adjusted CCRs for devices, including phasing in adoption of regression-adjusted device CCRs over several years, using the regression-adjusted CCRs to check the validity of early cost report data for the new cost center, and using the device regression-adjusted CCR to soften CCR changes due to new implantable devices cost report data.

Several commenters supported the use of regression-adjusted CCRs for drugs, but most commenters focused their comments about charge compression in drug payment on CMS' proposal to create two new cost centers for drugs with high and low pharmacy overhead costs, respectively, which is discussed in more detail in section V.B.3. of this final rule with comment period. Many commenters specifically opposed the concept of regression-adjusted CCRs for radiology services, noting that RTI's results for the CT Scanning and MRI cost centers were inaccurate due to error in capital cost allocation for specialized imaging services which resulted in inappropriately low relative weights.

Response: As noted above in the preceding three paragraphs, we once again received numerous mixed comments on the use of regression-adjusted CCRs, comparable to the type of comments received on the FY 2009 IPPS proposed rule. While we appreciate commenters' continued thoughtful comments on this issue, we did not propose to adopt regression-adjusted CCRs for the CY 2009 OPPS, as we have received mixed support for this approach in the past. As such, we are not implementing regression-adjusted CCRs for CY 2009. We continue to emphasize our preference for long-term cost reporting changes and broad education initiatives to address the accuracy of the data, rather than short-term statistical adjustments. With regard to devices, CMS finalized a proposal in the FY 2009 IPPS final rule to disaggregate the medical supplies CCR into one cost center for medical supplies and one for implantable devices (73 FR 48458 through 48467). This change to the cost report will influence both the IPPS and OPPS relative weights. We believe that, ultimately, improved and more precise cost reporting is the best way to minimize charge compression and improve the accuracy of the cost weights. With regard to radiology, we agree with the commenters that the hospital community could benefit from education on Medicare hospital cost report requirements for allocation of fixed capital and moveable equipment indirect costs to improve the accuracy of cost reporting for specialized imaging services.

RTI's third and final set of recommendations focused on long-term accounting revisions to the cost report and educational efforts to improve the overall accuracy of accounting data. RTI recommended: (1) Clarifying cost report instructions and requiring hospitals to use all standard lines in the cost report if their facility offers the described services; (2) creating new standard lines in the cost report for CT Scanning, MRI, Cardiac Catheterization, Devices, and Drugs Requiring Additional Coding; and (3) educating hospitals through industry-led educational initiatives directed at methods for capital cost finding, specifically encouraging providers to use direct assignment of equipment depreciation and lease costs wherever possible, or at least to allocate moveable equipment depreciation based on dollar value of assigned depreciation costs.

As noted above in this section, we will assess further steps we can take to educate hospitals about the principle of departmental apportionment of costs at § 413.53, which states that hospitals should apportion separately the costs and charges of each ancillary department for which charges are customarily made separately, rather than combining those costs and charges with another ancillary department. Standard cost centers are preprinted in the CMS-approved cost report software and constitute the minimum set of cost centers that must be reported on the Medicare hospital cost report as

required in Section 2302.8 of the PRM–I if the hospital creates a separate account for the service in its accounting system. RTI noted that many hospitals combine costs and charges for standard costs centers, especially therapeutic radiology and nuclear medicine services, under the diagnostic radiology cost center (RTI report, ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights,'' July 2008). In the CY 2009 OPPS/ASC proposed rule (73 FR 41431 through 41432), we specifically asked for public comment on the reasons for this aggregation and other relatively common deviations from cost reporting instructions, such as a failure to report the standard cost center 4700 (Blood Storing, Processing & Transportation) when the hospital bills Medicare for blood products that have storage and processing costs and charges.

With regard to creating new standard lines in the cost report, in addition to our proposal to add a standard cost center for Implantable Devices Charged to Patients in the FY 2009 IPPS proposed rule, we proposed to add two standard cost centers, one for Drugs with High Overhead Cost Charged to Patients and one for Drugs with Low Overhead Cost Charge to Patients, in the CY 2009 OPPS/ASC proposed rule. We discuss our decision not to finalize this proposal to create two new cost centers for drugs in our discussion of payment for the acquisition and pharmacy overhead costs associated with separately payable drugs and biologicals in section V.B.3. of this final rule with comment period.

As we indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41432), we believe that standard cost centers for CT Scanning, MRI, and Cardiac Catheterization also may be appropriate as we revise the Medicare hospital cost report form. CMS already has established nonstandard cost centers for these services and many hospitals currently report costs and charges for these cost centers. RTI identified almost 1,000 cost center lines for CT scanning, MRI, and cardiac catheterization each in the one year of HCRIS data used for RTI's study. Many more hospitals than this bill distinct charges for these services, and we are confident that many hospitals maintain a separate account for these services in their accounting system. While we currently use available nonstandard cost center CCRs for cost estimation under the OPPS, creating standard lines for common advanced imaging services, such as CT Scanning and MRI, and a common cardiac diagnostic service, Cardiac Catheterization, would encourage more providers to report cost and charge information separately for these services. Although we did not propose to create these cost centers, in the CY 2009 OPPS/ASC proposed rule (73 FR 41432), we specifically invited public comment on the appropriateness of creating standard cost centers for CT Scanning, MRI, and Cardiac Catheterization to consider in our revision of the Medicare hospital cost report form. We recognize that improved allocation of moveable equipment costs based on dollar value, the recommended allocation statistic, would be important to ensure improved accuracy in ratesetting if we were to make these cost centers standard.

The accuracy of capital cost allocation under Medicare allocation methods remains an issue when discussing the accuracy of CCRs for radiology and other capital-intensive services. We are supportive of industry-led educational initiatives to improve the quality of reporting capital costs in the cost report within the context of the Medicare policies in PRM–I, Section 2307, and PRM–II, Chapter 36, and, as we explained in the FY 2008 IPPS final rule with comment period (72 FR 47196), we are willing to work with the hospital industry to further such initiatives.

We received numerous comments about potential revisions to the cost report and recommendations to improve the cost report form and cost report process. A summary of the comments and our responses follow.

Comment: Many commenters urged CMS to use caution when making incremental changes to the cost report, but also suggested that a more comprehensive effort be made to improve the cost reporting process. Several commenters noted that changes to the cost report to improve the accuracy of prospective payment system weights impose hospital burden without adding additional revenue to the system and may counteract their purpose by requesting a level of precision that hospitals cannot provide. Some commenters requested that CMS make cost report changes consistent across the inpatient and outpatient payment systems. One commenter requested that CMS coordinate cost report requirements with those required by State Medicaid programs. Other commenters suggested that CMS undertake educational efforts providing greater detail on how to comply with regulations and manual instructions, how to file a cost report, how to evaluate a completed cost report for accuracy, and the consequences of noncompliance. Many commenters noted that hospitals do not know what CMS wants them to do when completing the cost report and urged CMS to provide explicit cost report guidance on direct expense assignment, capital expense assignment, allocation of overhead, and matching gross revenue, in order to reduce hospital reporting burden and to ensure that hospitals have both the direction and knowledge to comply. One commenter suggested that even if hospitals recognized problems in their internal cost reporting process, they would continue their erroneous reporting practice in order to achieve base year consistency. A number of commenters also requested that CMS instruct Medicare contractors to audit cost reports more closely.

Several commenters specifically addressed the new Implantable Devices Charged to Patients cost center finalized in the FY 2009 IPPS final rule. These commenters requested that CMS carefully choose an appropriate overhead allocation statistic to ensure that overhead allocation would not undermine the potential accuracy in CCR data behind CMS' proposal to create a new cost center. They requested that CMS undertake an educational campaign to describe appropriate practices for distinguishing between devices and supplies. Some commenters also requested that CMS develop mechanisms to validate the accuracy of data from the new cost center.

In response to CMS' inquiry regarding the failure of hospitals to report costs and charges for cost center 4700 (Blood Storing, Processing, and Transfusion), several commenters indicated that even though hospitals are required to bill costs and charges under revenue code 0391 (Administration, Processing and Storage for Blood and Blood Components; Administration (eg, Transfusion)) and capture those costs in cost center 4700 in the cost report, as indicated in the FY 2009 IPPS final rule (73 FR 48466), hospitals do not report costs and charges for cost center 4700 because there are no specific cost report instructions. The commenters suggested that CMS define a formula-driven expense reclassification method.

Response: We appreciate the thoughtful public input on clarifying cost report instructions and the cost reporting process. We recognize that there are areas of concern with the cost report, and we are taking steps to address some of them. These include finalizing a new cost center for implantable devices, adding fixed descriptions to HCRIS cost center codes in the cost report preparation software, and engaging in provider educational efforts to help educate providers

regarding the proper accounting of costs in the cost report. While these efforts are being made to help address charge compression and improve the accuracy of cost report data, more fundamentally, they will improve the cost reporting process itself.

We are currently in the process of making revisions to the Medicare cost report form, and we will consider the commenters' many concerns and recommendations summarized above in our revisions. Changes to the Medicare hospital cost report will be incorporated into both the IPPS and OPPS relative weights. Under the effort to update the cost report and eliminate outdated requirements in conjunction with the PRA, changes to the cost report form and cost report instructions will be made available to the public for comment. The commenters will have an opportunity to suggest more comprehensive reforms and to request more detailed instructions, and similarly will be able to make suggestions for ensuring that these reforms are made in a manner that is not disruptive to hospitals' billing and accounting systems and are within the guidelines of Medicare principles of reimbursement and generally accepted accounting principles (GAAP). We welcome further comment on changes to the revised Medicare hospital cost report through the PRA process.

Many State Medicaid programs use the Medicare cost report to determine Medicaid payments, including Medicaid Disproportionate Share Hospital (DSH) payments. Therefore, it is important for hospitals to complete the Medicare cost report in accordance with the Medicare reimbursement and cost reporting policies. With regard to reporting costs and charges for cost center 4700, we note that CMS provides instructions in PRM–II, Section 3610, Line 47 for this cost center.

While we always are open to incorporating refinements in our cost report instructions as requested by numerous commenters, we note that CMS cannot provide as much specificity in instructions as some commenters have requested, as discussed below. While CMS is responsible for issuing cost reporting instructions that are clear, hospitals are required to complete the cost report in a manner that is appropriate for their internal accounting system structure (42 CFR 413.20) and that is within the framework of Medicare reimbursement principles and cost report instructions. With regard to the overhead allocation basis for the new implantable devices cost center, CMS will recommend an allocation basis as it does with all overhead allocation. However, hospitals may use a different statistic if approved by the hospital's Medicare contractor, in accordance with PRM–I, Section 2313.

Comment: Many commenters did not support requiring hospitals to report all standard cost centers that describe services the hospitals provide.

Response: In accordance with the principle of departmental apportionment of costs at § 413.53, hospitals are required to report separately the costs and charges for each ancillary department for which charges are customarily billed. Section 2302.8 of the PRM–I defines a cost center as an organizational unit, generally a department or its subunit, having a common functional purpose for which direct and indirect costs are accumulated, allocated and apportioned. Language in the PRM–II, Chapter 36, incorporated these policies when establishing the standard ancillary cost centers in the cost report. Therefore, the standard cost centers constitute the most minimum set of common cost centers hospitals are required to report, assuming they maintain a separate account for those services in the internal accounting systems.

We recognize that not all cost centers, whether standard or nonstandard, apply to all providers. For example, where a provider furnishes all radiological services in a single department and their records are maintained in that manner, the provider would currently enter a single entry identifying all radiological services on the Radiology-Diagnostic line of Worksheet A and make no entries on the Radiology-Therapeutic line and Radioisotopes line of the cost report. However, currently, if these radiological services were furnished in three separate departments (cost centers), then the corresponding department data should also be accumulated as such in the provider's accounting system and recorded similarly in the cost report.

Comment: While some commenters expressed agreement in theory with establishing standard cost centers for CT Scanning, MRI, and Cardiac Catheterization, many expressed significant concern with their actual implementation. The commenters believed that allocating costs for these services to specific cost centers could prove difficult, especially for cardiac catheterization, and would in most cases be an estimate. Some commenters warned that smaller hospitals might not have accounting systems that allow matching costs to revenue in departments for these diagnostic services. One commenter suggested that hospitals frequently are slow to adopt new cost centers and that CMS should consider requiring all providers to use the new cost centers. Some commenters wanted to ensure that these services met CMS' definition for reporting as a separate and distinct cost center. A number of commenters requested that CMS delay implementation of these changes to the cost report to allow industry-led initiatives to improve cost reporting, especially capital cost finding, to take effect. Other commenters believed that the agency should fully understand hospital costs for CT and MRI before adding the standard cost centers. One commenter suggested that failure to establish cost centers for CT Scanning and MRI would amount to a violation of the Administrative Procedures Act (APA) because the final regulation must have some rational connection with the facts.

Response: RTI recommended these standard cost centers in order to separately capture cost and charge data for high volume services contributing to aggregation bias in the OPPS relative weights. Although we did not propose to adopt these cost centers as standard cost centers, we believe that doing so would help provide more accurate cost estimates for CT scans, MRI, and Cardiac Catheterization, coupled with improved hospital allocation of moveable equipment costs based on dollar value or direct assignment, if the criteria in PRM–I, Section 2307 are met. All of these departments already are nonstandard cost centers, and, therefore, we believe that they meet CMS' definition of separate and distinct cost centers, if a hospital maintains separate departments for these services and establishes separate accounts for them in its internal accounting system.

We will review these comments again, should we consider proposing additional standard cost centers in the cost report in future years.

We do not understand the comments concerning the APA. We did not propose to adopt these three cost centers; we only requested comment on RTI's recommendation. Further, RTI and commenters acknowledge that hospitals do not appear to be appropriately allocating capital costs to these specialized imaging cost centers, potentially using ''square feet'' as the allocation basis rather than the recommended allocation basis of ''dollar value.'' Finally, commenters will have an opportunity to provide further input on revisions to the Medicare hospital cost report form through a notice and comment process as we pursue changes to the cost report through the PRA process.

Comment: Many commenters asked CMS to consider whether separate cost centers for a variety of services should be created, such as Type B emergency departments, in order to develop more accurate CCRs, particularly in the context of potentially significant changes to the cost report form. Other commenters recommended that CMS limit cost report changes to cost center lines that have significant accuracy problems in their current CCRs, so as not to place undue burden on hospitals.

Response: The commenters will have an opportunity to provide further input on revisions to the Medicare hospital cost report form through the PRA notice and comment process anticipated later this year. We note that RTI could not consider Type B emergency department visits specifically in its analysis because Type B visits do not have a unique UB–04 revenue code. Still, most commenters believed that the issue of medical devices and supplies represented the most significant area of charge compression and further changes to the cost report and associated hospital reporting burden would not be warranted by potential improvements in payment accuracy. We understand the hospital's increased administrative burden that may result from changes to the cost report because we have been told that changes to the cost report involve significant accounting and billing modifications. However, we note that most of the cost centers discussed in this section are for departments or accounts that cost report data indicate are already established within many hospitals' internal accounting systems. As to the potential new billing requirements, we do not believe most cost report changes would require significant billing modifications if the hospital uses the most detailed UB–04 revenue codes available. In summary, we will keep these comments in mind as we consider other revisions to the Medicare hospital cost report.

Comment: Some commenters were very concerned with the results of RTI's analysis, which observed very low CCRs for CT scanning and MRI. They attributed this finding to a common hospital practice of allocating fixed capital and moveable equipment costs using a per square footage allocation statistic, rather than one that more appropriately associates the high capital and equipment costs with the CT and MRI cost centers. Some commenters believed that RTI's conclusions were unjustified because RTI assumed that the full cost of these specialized imaging services was fully captured by the CT and MRI nonstandard cost centers. Many commenters requested more guidance regarding how to properly allocate moveable equipment capital costs, including the practice of direct assignment of equipment depreciation and lease costs, and generally supported an educational initiative about capital cost finding. Most commenters supported allocating overhead based on direct assignment or dollar value of depreciation and lease costs.

Response: We agree that cost allocation of the capital costs (for example, depreciation or rental) of expensive moveable equipment using ''square feet'' as the allocation basis may lead to inaccuracies in cost estimates, as the allocation basis bears no direct relationship to the cost being allocated. Because the CMS-recommended allocation basis for moveable equipment capital costs is ''dollar value,'' we suggest that hospitals use that basis rather than ''square feet'' to allocate the moveable equipment capital costs. (We refer readers to Section 3617 of PRM–II and column header on Worksheet B–1.) We note that ''dollar value'' in the context of PRM–II, Section 3617 means the ''cost of the equipment'' rather than ''depreciation expense and lease costs'' as the commenters mentioned. We fully support industry-led hospital educational initiatives related to capital cost finding, including direct assignment. As to the cost finding, the policies in PRM–I, Section 2313 permit a hospital to request that its Medicare contractor approve a different allocation basis than the CMS-recommended basis if the use of the basis results in more appropriate and more accurate allocations. Hospitals may also directly assign the capital-related cost if such assignment meets all the criteria of PRM–I, Section 2307. However, we specify in PRM–I, Section 2307.A that, ''Direct assignment of cost is the process of assigning directly allocable costs of a general service cost center (we refer readers to Section 2302.9 of PRM–I) to all cost centers receiving service from that cost center based upon actual auditable usage'' and that, ''The direct assignment of costs must be made as part of the provider's accounting system with costs recorded in the ongoing normal accounting process.'' Therefore, these policies prohibit a hospital from directly assigning moveable equipment capital or building and fixture costs to, for example, only a CT Scanning, MRI, or Radiology-Diagnostic cost center(s), and allocating those moveable equipment capital or building and fixture costs applicable to all the other cost centers through the stepdown process. We note that these policies for allocating moveable equipment and building and fixture costs not only impact the accuracy of the OPPS cost estimates, but also impact the calculation of reimbursement for hospitals paid under cost reimbursement (such as cancer hospitals or CAHs).

2. Calculation of Median Costs

In this section of this final rule with comment period, we discuss the use of claims to calculate the final OPPS payment rates for CY 2009. The hospital OPPS page on the CMS Web site on which this final rule with comment period is posted provides an accounting of claims used in the development of the final rates at: *http://www.cms.hhs.gov/HospitalOutpatientPPS.* The accounting of claims used in the development of this final rule with comment period is included on the Web site under supplemental materials for the CY 2009 final rule with comment period. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, below we discuss the files of claims that comprise the data sets that are available for purchase under a CMS data user contract. Our CMS Web site, *http://www.cms.hhs.gov/HospitalOutpatientPPS*, includes information about purchasing the following two OPPS data files: ''OPPS Limited Data Set'' and ''OPPS Identifiable Data Set.'' These files are available for the claims that were used to calculate the final payment rates for the CY 2009 OPPS.

As proposed, we used the following methodology to establish the relative weights used in calculating the proposed OPPS payment rates for CY 2009 shown in Addenda A and B to this final rule with comment period.

a. Claims Preparation

We used the CY 2007 hospital outpatient claims processed on and before June 30, 2008, to set the final relative weights for CY 2009. To begin the calculation of the relative weights for CY 2009, we pulled all claims for outpatient services furnished in CY 2007 from the national claims history file. This is not the population of claims paid under the OPPS, but all outpatient claims (including, for example, 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 107 million claims that contain hospital bill types paid under the OPPS.

1. Claims that were not bill types 12X, 13X (hospital 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. In prior years, we also used claims of bill type 14X to set payment rates under the OPPS. However, bill type 14X ceased to be used to report any services for which payment is made under the OPPS effective April 1, 2006. Therefore, we did not use these claims in development of the final CY 2009 OPPS rates.

2. Claims that were bill types 12X or 13X (hospital bill types). These claims are hospital outpatient claims.

3. Claims that were bill type 76X (CMHC). (These claims are later combined with any claims in item 2 above with a condition code 41 to set the per diem partial hospitalization rate determined through a separate process.)

For the CCR calculation process, we used the same general approach as we used in developing the final APC rates for CY 2007 using the revised CCR calculation which 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 2007 before determining whether the CCRs for such hospitals were valid.

We then calculated the CCRs for each cost center and the overall CCR for each hospital for which we had claims data. We did this using hospital-specific data from the HCRIS. We used the most recent available cost report data, in most cases, cost reports beginning in CY 2006. As proposed, for this final rule with comment period, we used the most recently submitted cost reports to calculate the CCRs to be used to calculate median costs for the proposed CY 2009 OPPS 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 CCR, and we then adjusted the most recent available submitted but not settled cost report using that ratio. We calculated both an overall CCR and cost center-specific CCRs for each hospital. We used the overall CCR calculation discussed in section II.A.1.c. of this final rule with comment period for all purposes that require use of an overall CCR.

We then flagged 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 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, 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 CCR for the revenue code in question. 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 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.hhs.gov/HospitalOutpatientPPS*. Revenue codes not used to set medians or to model impacts are identified with an ''N'' in the revenue code-to-cost center crosswalk. We note that as discussed in section II.A.1.c.(1) of this final rule with comment period, we removed cost center 3580 (Recreational Therapy) from the hierarchy of CCRs for revenue code 0904 (Activity Therapy).

We then converted the charges to costs on each claim by applying the CCR that we believed was best suited to the revenue code indicated on the line with the charge. Table 2 of the CY 2009 OPPS/ASC proposed rule contained a list of the revenue codes we proposed to package. Revenue codes not included in Table 2 were those not allowed under the OPPS because their services could not be paid under the OPPS (for example, inpatient room and board charges), and thus charges with those revenue codes were not packaged during development of the OPPS median costs. One exception to this general methodology 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 final rule with comment period.

Thus, we applied CCRs as described above to claims with bill type 12X or 13X, 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. These claims were combined with the 76X claims identified previously to calculate the partial hospitalization per diem rate.

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 note that the separate file containing partial hospitalization claims is included in the files that are available for purchase as discussed above.

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, radiopharmaceutical agents, blood and blood products, and brachytherapy sources, as well as other information used to set payment rates, such as a unit-to-day ratio for drugs.

We did not receive any public comments on our CY 2009 proposal to prepare the claims to be split into usable groups and, therefore, we are finalizing our proposal without modification.

b. Splitting Claims and Creation of ''Pseudo'' Single 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.) In the CY 2009 OPPS/ASC proposed rule (73 FR 41434), we proposed to continue our current policy of defining major procedures as any procedure 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 2009, we proposed that status indicator ''R'' would be assigned to blood and blood products; status indicator ''U'' would be assigned to brachytherapy sources; status indicator ''Q1'' would be assigned to all ''STVX-packaged codes;'' status indicator ''Q2'' would be assigned to all ''T-packaged codes;'' and status indicator ''Q3'' would be assigned 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. The codes with proposed status indicators ''Q1,'' ''Q2,'' and ''Q3'' were previously assigned status indicator ''Q'' for the CY 2008 OPPS. As we discuss in section XIII.A.1. of this final rule with comment period, we proposed to assign these new status indicators to facilitate identification of the different categories of codes. We proposed to treat these codes in the same manner for data purposes for CY 2009 as we treated them for CY 2008. Specifically, we proposed 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 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 major claims is discussed in section II.A.2.e. of this final rule with comment period.

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

1. *Single 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 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 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 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 either a code for a separately paid OPPS service or a code for a packaged 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 files 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 final rule with comment period. Claims that contain codes to which we have assigned status indicator ''Q3'' (composite APC members) appear in both the data of the single and multiple major files used in this final rule with comment period, depending on the specific composite calculation.

Comment: One commenter asked that CMS make the preliminary packaging and composite data available to the public for review as soon as possible. In addition, several commenters requested that CMS make packaging data available to the public, including utilization rates and median costs for packaged services, and general payment calculations, to allow more transparency in the OPPS ratesetting process.

Response: We make available a considerable amount of data for public analysis each year and, while we are not developing and providing to the public the extensively detailed information that commenters requested, we provide the public use files of claims and a detailed narrative description of our data process that the public can use to perform any desired analyses. In addition, we believe that the commenters must examine the data themselves to develop the specific arguments to support their requests for changes to payments under the OPPS. In fact, several commenters submitted detailed analyses of how often certain packaged services were provided with specific independent services, and the amount by which packaged costs contribute to the payment rate for the

independent service. We understand that the OPPS is a complex payment system and that it is impossible to easily determine the quantitative amount of packaged costs present in the median cost for every independent service. However, based on the complex and detailed comments that we received, commenters are clearly able to perform meaningful analyses based on the public claims data available at this time.

After consideration of the public comments received on our proposed process of organizing claims by type, we are finalizing our CY 2009 proposal, without modification.

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

As proposed, to develop ''pseudo'' single claims for this final rule with comment period, we examined both the multiple major claims and the multiple minor claims. We first examined the multiple major 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 paid 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 final rule with comment period 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. 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 claims by dividing the cost for the multiple units by the number of units on the line. Where one unit of a single, separately paid procedure code remained on the claim after removal of the multiple units of the bypass code, we created a ''pseudo'' single 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.

Where only one unit of one of an ''overlap bypass code'' appeared on a claim with only one unit of another separately paid code, for the CY 2009 OPPS/ASC proposed rule we used the line-item cost of the ''overlap bypass code'' to create a ''pseudo'' single procedure claim for the ''overlap bypass code'' but did not use the remaining costs on the claim for the other separately paid procedure.

Comment: Several commenters urged CMS to use as much claims data as possible to set the CY 2009 OPPS median costs.

Response: We agree that it is preferable to use as much claims data as possible to maximize the extent to which the median costs for any given service or APC accurately reflect the relative costs of the services. Although as discussed in section II.A.1.b. of this final rule with comment period, the removal of radiation oncology codes that did not pass the empirical criteria from the bypass list for this final rule with comment period resulted in a smaller number of ''pseudo'' single claims, we were able to revise our treatment of the ''overlap bypass codes'' to enable us to use the claims data that remained on the claim after removal of the line-item cost for the bypass code when only one unit of one separately paid code remained on the claim. We refer readers to section II.A.1.b. of this final rule with comment period for further discussion of this change.

For this final rule with comment period, we created ''pseudo'' single claims from the remaining information on these claims. We assessed 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 paid code remained on the claim. If so, we attributed the packaged costs on the claim to the single unit of the single remaining separately paid code other than the bypass code to create a ''pseudo'' single claim. This allowed us to use more claims data for ratesetting purposes for this final rule with comment period.

We also examined the multiple 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 2008 relative weight, moved the units to one on that HCPCS code, and packaged all costs for other codes with status indicator ''Q1,'' as well as all other packaged HCPCS code and packaged revenue code costs, into a total single cost for the claim to create a ''pseudo'' single claim for the selected code. 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 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 2008 relative weight, moved the units to one on that HCPCS code, and packaged all costs for other codes with status indicator ''Q2,'' as well as all other packaged HCPCS code and packaged revenue code costs into a total single cost for the claim to create a ''pseudo'' single claim for the selected code. 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 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 2008, moved the units to one on that HCPCS code, and packaged all costs for other codes with status indicator ''Q2,'' costs of all codes with status indicator ''Q1'' (''STVX-packaged''), and other packaged HCPCS code and packaged revenue code costs into a total single cost for the claim to create a ''pseudo'' single claim for the selected (''T-packaged'') code. We favor status indicator ''Q2'' over ''Q1'' HCPCS codes because ''Q2'' HCPCS codes have higher CY 2008 relative weights. If a status indicator ''Q1'' HCPCS code had a higher CY 2008 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.

After we assessed the conditional packaging of HCPCS codes with proposed status indicators ''Q1'' and

''Q2,'' we then assessed the claims to determine if the criteria for the multiple imaging composite APCs, discussed in section II.A.2.e.(5) of this final rule with comment period, were met. 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.

We excluded those claims that we were not able to convert to single claims even after applying all of the techniques for creation of ''pseudo'' singles to multiple majors and to multiple minors. 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 the code appeared with a unit of one.

Comment: One commenter suggested that the handling of status indicator ''Q1'' (''STVX-packaged'') and ''Q2'' (''T-packaged'') conditionally packaged codes at the beginning of the ratesetting process rather than in later stages packaged more lines than were necessary or appropriate. The commenter suggested that applying the packaging determination of the conditionally packaged code in later stages would allow lines that would otherwise be packaged to be used for ratesetting.

Response: The purposes of the various methods through which we develop ''pseudo'' single claims is to isolate the resource cost of a service in situations where that otherwise might not be possible. In the case of the status indicator ''Q1'' and ''Q2'' conditionally packaged codes, we only used lines that would actually be paid separately under the final CY 2009 payment policies in estimating median costs in order to accurately estimate the costs of these services when they would be separately payable. The commenter's suggested methodology would result in our incorporation of lines that would be packaged when processed through the I/OCE, which we believe to be inappropriate in the ''pseudo'' single claim development process that we use to estimate the costs of services that would be separately payable.

After consideration of the public comment received, we are finalizing our CY 2009 proposal, without modification, for the process by which we develop ''pseudo'' single claims, for this final rule with comment period.

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 final rule with comment period, the costs of those lines for codes with status indicator ''Q1'' or ''Q2'' when they are not separately paid), and the costs of packaged revenue codes 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 requires CMS to review the final list of packaged revenue codes for consistency with OPPS policy and ensure that future versions of the I/OCE edit accordingly. We compared the packaged revenue codes in the I/OCE to the final list of packaged revenue codes for the CY 2008 OPPS (72 FR 66608 through 66609) and that we used for packaging costs in median calculation. As a result of that analysis, we used the packaged revenue codes for CY 2009 that are displayed in Table 2 below. We received no public comments on the revenue codes that we proposed to package for CY 2009 and, therefore, we are finalizing the list of packaged revenue codes as proposed, without modification, as shown in Table 2 below.

In this final rule with comment period, 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 description of the revenue code categories and subcategories to better articulate the meanings of the revenue codes. However, while the labeling for the packaged revenue codes changed, the list of revenue codes shown in Table 2 has not changed from the revenue codes that we proposed to package for CY 2009 as displayed in Table 2 of the CY 2009 OPPS/ASC proposed rule (73 FR 41436 through 41437) and which we are finalizing for the CY 2009 OPPS. In the course of making the changes in labeling for the revenue codes in Table 2, we noticed some changes to revenue categories and subcategories that we believe warrant further review for future OPPS updates. Although we are finalizing the list of packaged revenue codes in Table 2 for CY 2009, we intend to assess the NUBC revenue codes to determine whether any changes to the list of packaged revenue codes should be proposed for the CY 2010 OPPS. We welcome public input and discussion during the comment period of this final rule with comment period on the packaged revenue codes listed in Table 2, for purposes of assisting us in this assessment of revenue codes. When submitting comments, commenters should remember that the OPPS pays not only for services furnished to hospital outpatients but also pays for a limited set of services furnished to inpatients who do not have Part A coverage of hospital services furnished on the date on which the service is furnished. Payment under the OPPS for these services, which are reported on 12X bill types, may lead to the appropriate packaging of some costs reported on inpatient revenue codes for purposes of the OPPS ratesetting.

TABLE 2—CY 2009 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.

TABLE 2—CY 2009 PACKAGED REVENUE CODES—Continued

Revenue code	Description
0260	IV Therapy; General Classification.
0262	IV Therapy; IV Therapy/Pharmacy Svcs.
0263	IV Therapy; IV Therapy/Drug/Supply Delivery.
0264	IV Therapy; IV Therapy/Supplies.
0269	IV Therapy; Other IV Therapy.
0270	Medical/Surgical Supplies and Devices; General Classification.
0271	Medical/Surgical Supplies and Devices; Non-sterile Supply.
0272	Medical/Surgical Supplies and Devices; Sterile Supply.
0273	Medical/Surgical Supplies and Devices; Take Home Supplies.
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.
0399	Administration, Processing and Storage for Blood and Blood Components; Other Blood Handling.
0560	Home Health (HH)—Medical Social Services; General Classification.
0569	Home Health (HH)—Medical Social Services; Other Med. Social Service.
0621	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Radiology.
0622	Medical Surgical Supplies—Extension of 027X; Supplies Incident to Other DX Services.
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.
0709	Cast Room; Reserved.
0710	Recovery Room; General Classification.
0719	Recovery Room; Reserved.
0720	Labor Room/Delivery; General Classification.
0721	Labor Room/Delivery; Labor.
0732	EKG/ECG (Electrocardiogram); Telemetry.
0762	Specialty Room—Treatment/Observation Room; Observation Room.
0801	Inpatient Renal Dialysis; Inpatient Hemodialysis.
0802	Inpatient Renal Dialysis; Inpatient Peritoneal Dialysis (Non-CAPD).
0803	Inpatient Renal Dialysis; Inpatient Continuous Ambulatory Peritoneal Dialysis (CAPD).
0804	Inpatient Renal Dialysis; Inpatient Continuous Cycling Peritoneal Dialysis (CCPD).
0809	Inpatient Renal Dialysis; Other Inpatient Dialysis.
0810	Acquisition of Body Components; General Classification.
0819	Inpatient Renal Dialysis; Other Donor.
0821	Hemodialysis-Outpatient or Home; Hemodialysis Composite or Other Rate.
0824	Hemodialysis-Outpatient or Home; Maintenance—100%.
0825	Hemodialysis-Outpatient or Home; Support Services.
0829	Hemodialysis-Outpatient or Home; Other OP Hemodialysis.
0942	Other Therapeutic Services (also see 095X, an extension of 094x); Education/Training.

In addition, we excluded (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 for a service with status indicator ''S'' or ''T'' (a major separately paid 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 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.

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 proposed 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.

We also excluded claims that were 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 58 million claims were left for this final rule with comment period. Using these 58 million claims, we created approximately 99 million single and ''pseudo'' single claims, of which we used 99 million single bills (after trimming out approximately 617,000 claims as discussed above in this section) in the final CY 2009 median development and ratesetting.

We used the remaining claims to calculate the final CY 2009 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 and public comments received on the CY 2009 OPPS/ASC proposed rule and reassigned HCPCS codes to different APCs where we believed that it was appropriate. Section III. of this final rule with comment period includes a discussion of certain HCPCS code assignment changes that resulted from examination of the median costs, review of the public comments, 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 bills.

Comment: Several commenters objected to the volatility of the OPPS rates from year to year. These commenters asserted that the absence of stability in the OPPS rates creates budgeting, planning, and operating problems for hospitals, and that as more care is provided on an outpatient, rather than inpatient basis, the need for stable payment rates from one year to the next becomes more important to hospitals. Some commenters suggested that we limit reductions in APC payments to a set amount. One commenter suggested that we reexamine the billing system.

Response: There are a number of factors pertinent to the OPPS that may cause median costs to change from one year to the next. Some of these are a reflection of hospital behavior, and some of them are a reflection of fundamental characteristics of the OPPS as defined in statute. For example, the OPPS payment rates are based on hospital cost report and claims data. However, hospital costs and charges change each year and this results in both changes to the CCRs taken from the most currently available cost reports and also differences in the charges on the claims that are the basis of the calculation of the median costs on which OPPS rates are based. Similarly, hospitals adjust their mix of services from year to year by offering new services and ceasing to furnish services or changing the proportion of the various services they furnish, which has an impact on the CCRs that we derive from their cost reports. CMS cannot stabilize these hospital-driven fundamental inputs to the calculation of OPPS payment rates.

Moreover, there are other essential elements of the OPPS which contribute to the changes in relative weights each year. These include, but are not limited to, reassignments of HCPCS codes to APCs to rectify 2 times violations as required by the law, to address the costs of new services, to address differences in hospitals' costs that may result from changes in medical practice, and to respond to public comments. Our efforts to improve payment accuracy may also contribute to payment volatility in the short run, as may be the case when we are eventually able to use more specific CCRs to estimate the costs of implantable devices, based on the final policy that we adopted to disaggregate the single cost center for medical supplies into two more specific cost centers, as described in the FY 2009 IPPS final rule (73 FR 48458 through 48467). Moreover, for some services, we cannot avoid using small numbers of claims, either because the volume of services is naturally low or because the claims data do not facilitate the calculation of a median cost for a single service. Where there are small numbers of claims that are used in median calculation, there is more volatility in the median cost from one year to the next. Lastly, changes to OPPS payment policy (for example, changes to packaging) also contribute to some extent to the fluctuations in the OPPS payment rates for the same services from year to year.

We cannot avoid the naturally occurring volatility in the cost report and claims data that hospitals submit and on which the payment rates are based. Moreover (with limited exceptions), we are required by law to reassign HCPCS codes to APCs where it is necessary to avoid 2 times violations. However, we have made other changes to resolve some of the other potential reasons for instability from year to year. Specifically, we continue to seek ways to use more claims data so that we have fewer APCs for which there are small numbers of single bills used to set the APC median costs. Moreover, we have tried to eliminate APCs with very small numbers of single bills where we could do so. We recognize that changes to payment policies, such as the packaging of payment for ancillary and supportive services and the implementation of composite APCs, may contribute to volatility in payment rates in the short term, but we believe that larger payment packages and bundles should help to stabilize payments in future years by enabling us to use more claims data and by establishing payments for larger groups of services.

Comment: Some commenters asked that CMS provide an adjustment for medical education costs under the OPPS because many of the costs of teaching services are now incurred in the HOPD as services previously furnished only in the inpatient setting are now being furnished in the HOPD. These commenters stated that CMS indicated that it would study the costs and payment differential among different classes of providers in the April 7, 2000 OPPS final rule but has not done so. They recommended that CMS study whether the hospital outpatient costs of teaching hospitals are higher than the costs of other hospitals for purposes of determining whether there should be a teaching hospital adjustment. The

commenters explained that their internal analysis of 2006 Medicare cost reports showed that the average outpatient margins were −27.3 for major teaching hospitals, −13.0 for other teaching hospitals, and −15.2 for nonteaching hospitals. They believed that these findings demonstrated that the hospital outpatient costs of major teaching hospitals are significantly greater than the costs of other hospitals. The commenters requested that CMS conduct its own analysis and that if that analysis showed a difference due to the unique missions of teaching hospitals, CMS should add a teaching adjustment to the OPPS.

Response: Unlike payment under the IPPS, the law does not provide for payment for indirect medical education costs to be made under the OPPS. Section 1833(t)(2)(E) of the Act, as added by section 4523 of the BBA, states that the Secretary shall establish, in a budget neutral manner ''* * * other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.'' We have not found such an adjustment to be necessary to ensure equitable payments to teaching hospitals and, therefore, have not developed such an adjustment. We do not believe an indirect medical education add-on payment is appropriate in a budget neutral payment system where such changes would result in reduced payments to all other hospitals. Furthermore, in this final rule with comment period, we have developed payment weights that we believe provide appropriate and adequate payment for the complex medical services, such as visits requiring prolonged observation, new technology services, and device-dependent procedures, which we understand are disproportionately furnished by teaching hospitals. We note that teaching hospitals benefit from the CY 2009 recalibration of the APCs in this final rule with comment period. The final CY 2009 impacts by class of hospital are displayed in Table 51 in section XXIII.B. of this final rule with comment period.

After consideration of the public comments received, we are finalizing our proposed CY 2009 methodology for calculating the median costs upon which the CY 2009 OPPS payment rates are based.

In some cases, APC median costs are calculated using variations of the process outlined above. Section II.A.2.d. of this final rule with comment period that follows addresses the calculation of single APC criteria-based median costs. Section II.A.2.e. of this final rule with comment period discusses the calculation of composite APC criteria-based median costs. Section X.B. of this final rule with comment period addresses the methodology for calculating the median cost for partial hospitalization services.

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

(1) Device-Dependent APCs

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

In the CY 2009 OPPS/ASC proposed rule (73 FR 41437), we proposed for CY 2009 to continue using our standard methodology for calculating median costs for device-dependent APCs, which utilizes claims data that generally represent the full cost of the required device. Specifically, we proposed to calculate the medians for device-dependent APCs for CY 2009 using only the subset of single procedure claims from CY 2007 claims data that pass the procedure-to-device and device-to-procedure edits; do not contain token charges (less than $1.01) for devices; and 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. We believe that this methodology gave us the most appropriate proposed rule median costs for device-dependent APCs in which the hospital incurs the full cost of the device.

While the median costs for the majority of device-dependent APCs showed increases from CY 2008 based on the CY 2009 proposed rule claims data, the median costs for three APCs involving electrode/lead implantation decreased significantly compared to the CY 2008 final rule with comment period median costs. Specifically, APC 0106 (Insertion/Replacement of Pacemaker Leads and/or Electrodes), APC 0225 (Implantation of Neurostimulator Electrodes, Cranial Nerve), and APC 0418 (Insertion of Left Ventricular Pacing Electrode) demonstrated median decreases of 26 percent, 52 percent, and 47 percent, respectively. As indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41437), we believe these decreases reflect hospitals' correction of inaccurate and incomplete billing practices for these services due to the implementation of device-to-procedure edits beginning in CY 2007. As discussed in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68070 through 68071), in the course of examining claims data for calculation of the CY 2007 OPPS payment rates, we identified circumstances in which hospitals billed a device code but failed to bill any procedure code with which the device could be used correctly. For APCs 0106, 0225, and 0418 in particular, we found that hospitals frequently billed a procedure code for lead/electrode implantation with device HCPCS codes for a lead/electrode and the more expensive pulse generator but failed to report a procedure code for generator implantation. These errors in billing led to the costs of the pulse generator being packaged incorrectly into the procedure codes for lead/electrode implantation. Hospitals that coded and billed in this manner received no payment for the procedure to implant the pulse generator, but these erroneous claims caused the OPPS payment rate for the lead/electrode implantation APCs to be inappropriately high. To address this problem, we implemented edits to correct the coding for CY 2007, and the proposed decreases to the median costs of APCs 0106, 0225, and 0418 for CY 2009 were consistent with what we expected, based on what we understood to be the nature of the services and the costs of correctly coded devices. In the CY 2009 OPPS/ASC proposed rule (73 FR 41438), we also noted an anticipated decrease in our frequency of single procedure claims for the services assigned to APCs 0106, 0225, and 0418, most likely because the device-to-procedure edits led hospitals to include the pulse generator implantation HCPCS codes on the same claims, resulting in fewer single procedure claims for the lead/electrode implantation procedures.

At the August 2008 meeting of the APC Panel, one presenter stated that the proposed decrease in payment for CY 2009 for APC 0225, which includes a procedure to implant a neurostimulator electrode for vagus nerve stimulation (VNS), would make VNS too costly for

providers and beneficiaries relative to its OPPS payment. The presenter requested that CMS reassign CPT code 64553 (Percutaneous implantation of neurostimulator electrodes, cranial nerve) to APC 0040 (Percutaneous Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve), leaving CPT code 64573 (Incision for implantation of neurostimulator electrodes, cranial nerve) as the only code in APC 0225 (CPT code 64573 describes the lead implantation for VNS). The presenter argued that the procedure described by CPT code 64553 is more similar clinically and in terms of resource utilization to the procedures assigned to APC 0040 than to the other procedure assigned to APC 0225. The presenter also requested that, after reassigning CPT code 64553 to APC 0040, CMS calculate the payment rate for APC 0225 using only claims for patients with epilepsy. According to the presenter, in May 2007, CMS issued a National Coverage Determination (NCD) denying Medicare coverage of VNS for the treatment of depression, while maintaining coverage for certain epilepsy indications. The presenter stated that it was possible the Medicare noncoverage of VNS for depression may have confused hospital providers, leading to incorrect hospital coding and submission of epilepsy claims. In response to this two-part request, the APC Panel recommended that CMS reassign CPT code 64553 to APC 0040, and that CMS recalculate the median cost of APC 0225 based solely on claims for CPT code 64573. The APC Panel did not make a recommendation related to the requester's second request, to include only claims with epilepsy indications in ratesetting for APC 0225. We discuss our response to these two APC Panel recommendations below under the comments and responses section of this section of this final rule with comment period.

We also indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41438), that APC 0625 (Level IV Vascular Access Procedures) as configured for CY 2008 and calculated based on CY 2007 claims data also demonstrated a significant decrease in median cost (approximately 59 percent) relative to CY 2008 (based on CY 2006 claims data). We believe this decrease is attributable to the implementation of procedure-to-device edits on January 1, 2007, for the only CPT code assigned to this APC, specifically CPT code 36566 (Insertion of tunneled centrally inserted central venous access device, requiring two catheters via two separate venous access sites; with subcutaneous port(s)). Because the procedure described by CPT code 36566 involves the insertion of a dialysis access system, our edits require that the HCPCS code for that device be present on the claim any time a hospital bills CPT code 36566. Prior to January 1, 2007, we believe that hospitals often reported CPT code 36566 without also reporting the device HCPCS code for the dialysis access system, or incorrectly billed CPT code 36566 for procedures that do not require the use of the device. Therefore, with the implementation of procedure-to-device edits, the volume of total CY 2007 claims for CPT code 36566 decreased as hospitals corrected their claims to report this service only under the appropriate circumstances, while the correctly coded claims reporting the required device (and available for CY 2009 ratesetting) increased significantly from CY 2006 to CY 2007. We believe that the CY 2009 proposed rule median cost of approximately $2,092 calculated for CPT code 36566 from those claims was accurate and appropriately reflected correct hospital reporting of the procedure and the associated device. Furthermore, because of the decrease in the median cost for CPT code 36566, we proposed to reassign the code to APC 0623 (Level III Vascular Access Procedures), which had a proposed median cost of approximately $1,939. We also proposed to delete APC 0625 because no other procedures would map to this APC if CPT code 36566 was reassigned.

In addition, we noted a decrease of approximately 19 percent for APC 0681 (Knee Arthroplasty) relative to CY 2008, which we believe is attributable to a low volume of services being performed by a small number of providers (73 FR 41438) and to a single provider furnishing the majority of the 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, particularly for low volume device-dependent APCs such as APC 0681, for which the proposed median cost increased approximately 37 percent from CY 2007 to CY 2008.

Comment: Many commenters supported the CMS proposal to set the median costs for device-dependent APCs using the standard device-dependent APC ratesetting methodology in CY 2009, and expressed appreciation of CMS' efforts to use only those claims that reflect the full costs of devices in ratesetting for device-dependent APCs. One commenter remarked that the methodology of using only those claims that include the appropriate device HCPCS codes to calculate payment rates for procedures that require a device to be implanted or used results in payment rates that more appropriately reflect the costs associated with device-dependent APCs. The commenter supported the proposed payment increases for APC 0385 (Level I Prosthetic Urological Procedures) and APC 0386 (Level II Prosthetic Urological Procedures) in particular. Some commenters supported the mandatory reporting of all HCPCS device C-codes, and urged CMS to continue educating hospitals on the importance of accurate coding for devices, supplies, and other technologies. Those commenters recommended that CMS focus on educating providers on the accurate use of supply codes, particularly HCPCS code A4306 (Disposable drug delivery system, flow rate of less than 50 ml per hour), which the commenters believed was reported inappropriately by many hospitals.

Several commenters also requested that CMS exclude claims from ratesetting in CY 2010 and beyond that contain the ''FC'' modifier, indicating the procedure was performed using a device for which the hospital received partial credit. According to the commenters, exclusion of these claims is necessary to ensure that only claims that contain the full costs of devices are included in ratesetting.

Response: We appreciate the commenters' support of the standard device-dependent APC ratesetting methodology. We agree that accurate reporting of device, supply, and technology charges will help to ensure that these items are appropriately accounted for in future years' OPPS payment rates. We encourage stakeholders to carefully review HCPCS code descriptors, as well as any guidance CMS may have provided for specific HCPCS codes. In addition, we have provided further instructions on the billing of medical and surgical supplies in the October 2008 OPPS update (Transmittal 1599, Change Request 6196, dated September 19, 2008). For HCPCS codes that are paid under the OPPS, providers may also submit inquiries to the AHA Central Office on HCPCS, which serves as a clearinghouse on the proper use of Level I HCPCS codes for hospital providers and certain Level II HCPCS codes for hospitals, physicians, and other health professionals. Inquiries must be submitted using the approved form, which may be downloaded from the AHA Web site (*http://www.ahacentraloffice.org*) and either faxed to 312–422–4583 or mailed directly to the AHA Central Office: Central Office on HCPCS, American

Hospital Association, One North Franklin, Chicago, IL 60606.

The ''FC'' modifier became effective January 1, 2008, and will be present for the first time on claims used in OPPS ratesetting for CY 2010. Any refinements to our standard device-dependent APC ratesetting methodology for years beyond CY 2009 would be addressed in future rulemaking.

Comment: Several commenters remarked that the CY 2009 OPPS/ASC proposed rule included several reductions to the payments for device-dependent APCs that they believe may threaten medical technology innovation and patient access. The commenters made the general recommendation that CMS study further the claims for any APC for which the calculated payment reduction would be greater than 10 percent and take action to correct issues that may reduce these payments artificially. The commenters further recommended that CMS limit the reduction in payment that any device-dependent APC may experience in 1 year to 10 percent. Other commenters expressed concerns specifically about the proposed payment reductions for APCs 0106 and 0418, arguing that the proposed payment rates would not cover outpatient hospital costs associated with providing the procedures assigned to these APCs, and that CMS should take steps to stabilize payment for these APCs to protect beneficiary access.

Several commenters also requested that CMS reassign CPT code 64553 from APC 0225 to APC 0040 as a means to address what they perceived to be inadequate payment for the only other procedure assigned to APC 0225, which is described by CPT code 64573, consistent with the recommendation made by the APC Panel at its August 2008 meeting. These commenters argued that the procedure described by CPT code 64553 is more similar clinically and/or in terms of resource utilization to procedures that are assigned to APC 0040, because these procedures have median costs that more closely approximate the median cost of CPT code 64553 and involve the percutaneous implantation of neurostimulator electrodes through an introducer needle. They asserted that CPT code 64573, in contrast, describes electrode placement by using a scalpel to incise skin. In addition to requesting the reassignment of CPT code 64553 to APC 0040, some commenters asked CMS to calculate the median cost for CPT code 64573 using only single procedure claims with an epilepsy diagnosis code that is consistent with CMS' NCD for VNS, effective May 4, 2007.

Response: We do not agree that it is necessary to implement a payment reduction limit of 10 percent or take other steps to stabilize payment for device-dependent APCs in CY 2009. We reviewed the data for all device-dependent APCs with significant changes in median costs from CY 2008 to CY 2009, as is our usual practice, to ensure there are no data errors that would inappropriately or artificially impact the median costs. We found no reason to believe that the claims used to calculate the median costs for all device-dependent APCs, including those with median costs that declined for CY 2009 relative to CY 2008, did not appropriately reflect hospitals' relative costs for providing those services as reported to us in the claims and cost report data. Because we believe the device-dependent APC median costs appropriately reflect hospital costs, implementing a payment reduction limit would artificially and inaccurately inflate payment rates. As described previously in this section and in the CY 2009 OPPS/ASC proposed rule (73 FR 41437 through 41438), the decreases in median costs for three APCs involving electrode/lead implantation, APCs 0106, 0225, and 0418, are expected and appropriate based on what we understand to be the nature of the services included in these APCs and the costs of correctly coded devices. We believe that the median costs calculated for these APCs were inappropriately high in years prior to CY 2009 due to widespread errors in how hospitals billed for the implantation of leads/electrodes and the pulse generators connected to the leads/electrodes. Prior to CY 2007, hospitals frequently billed a procedure code for lead/electrode implantation with device HCPCS codes for a lead/electrode *and* the more costly pulse generator, but failed to report a procedure code for the implantation of the pulse generator. As a result, hospitals received only one APC payment for implanting both the electrode/lead and the pulse generator when they should have received separate APC payments for both the electrode/lead implantation and the pulse generator implantation. These hospital billing errors also resulted in the inappropriate attribution of the pulse generator costs to the median costs for the APCs for the less expensive electrode/lead implantation procedures.

The implementation of device-to-procedure edits in CY 2007 corrected these incorrect and incomplete billing practices by requiring hospitals to include a procedure code for pulse generator implantation when they report a device HCPCS code for a pulse generator or to remove the device HCPCS code for the pulse generator from the claim if it was not furnished. As described above in this section, prior to CY 2007, some hospitals billed a procedure code for lead/electrode implantation with device HCPCS codes for both a lead/electrode and the more costly pulse generator, but did not bill a procedure code for implantation of the pulse generator. This practice resulted in an erroneous single procedure claim that was used for ratesetting in years prior to CY 2009. However, beginning in CY 2007, hospitals reported such services with a procedure code for lead/electrode implantation, a device HCPCS code for the lead/electrode, a procedure code for pulse generator implantation, and a device HCPCS code for the pulse generator (resulting in a multiple procedure claim that would not be used for ratesetting). Thus, for the first time in CY 2009, we no longer have single procedure claims available for ratesetting that would result in the inappropriate attribution of pulse generator costs to lead/electrode implantation APCs. Where the edits result in hospitals billing both the CPT code for the insertion of the leads and the CPT code for the implantation of the device, hospitals are being correctly paid considerably more than they were being paid when they were billing incorrectly. Therefore, we believe that the device-to-procedure edits result both in more accurate claims payment and more appropriate relative weights for these services.

We agree with the commenters and the APC Panel that the procedure described by CPT code 64553 is more similar clinically and in terms of resource utilization to procedures that are assigned to APC 0040 than to the other procedure assigned to APC 0225. Therefore, for CY 2009, we are accepting the APC Panel's recommendation and reassigning the procedure described by CPT code 64553 to APC 0040, and changing the title of APC 0040 to ''Percutaneous Implantation of Neurostimulator Electrode.'' As a result of our decision to reassign CPT code 64553 from APC 0225 to APC 0040, CPT code 64573 is the only CPT code assigned to APC 0225. Consistent with the APC Panel's second recommendation, we are recalculating the median cost of APC 0225 based solely on claims for CPT code 64573.

We do not agree with the commenters that we should calculate the median cost for CPT code 64573 using only single procedure claims with an epilepsy diagnosis code based on CMS'

NCD for VNS therapy, effective May 4, 2007. OPPS payment rates typically apply regardless of the medical condition for which a device is used; thus, APC median costs are developed based on claims for all patient diagnoses. Furthermore, we note that the NCD for VNS made effective on May 4, 2007, establishes noncoverage of VNS specifically for indications of depression. We examined the diagnosis codes present on the single procedure claims for CPT code 64573 that we would use in ratesetting, and found that, while diagnosis codes for epilepsy most commonly appeared on the claims, most nonepilepsy diagnoses present on the claims were for conditions other than depression. As such, the recommendation by some commenters to utilize only those claims with an epilepsy diagnosis for ratesetting would result predominantly in the exclusion of claims with diagnoses other than depression, to which the VNS national noncoverage decision does not apply. Therefore, we find no basis to deviate from our standard device-dependent APC ratesetting methodology, which does not take into consideration patient diagnoses, and we will not exclude claims for VNS therapy with diagnoses other than epilepsy from ratesetting.

Comment: One commenter stated that, while the standard device-dependent APC ratesetting methodology of using single procedure claims for calculating median costs is appropriate for many device-dependent APCs, this approach distorts and undervalues payment for those services where multiple device-dependent procedures are conducted within the same session. The commenter pointed out, as an example, that the lead/electrode implantation procedures assigned to APC 0225 are frequently performed with pulse generator implantation procedures assigned to APC 0039 (Level I Implantation of Neurostimulator). The commenter also noted that, according to an analysis of CY 2007 claims data available for the CY 2009 OPPS/ASC proposed rule, claims for device-dependent APCs more commonly include multiple procedures than claims for other types of APCs. The commenter encouraged CMS to develop a methodology to ensure that packaged costs can be allocated across multiple procedures performed on the same date of service. Until such a methodology can be implemented, the commenter asked that CMS institute a payment reduction limit of no more than 10 percent annually for device-dependent APCs such as APC 0225 with a large proportion of multiple procedure claims. Other commenters shared similar concerns about the use of single procedure claims in ratesetting for device-dependent APCs and suggested that CMS implement a composite payment methodology for certain procedures assigned to device-dependent APCs for which relatively few correctly coded single procedure claims are available for ratesetting, specifically those procedures involving the implantation of a cardiac resynchronization therapy defibrillator (CRT–D) or cardiac resynchronization therapy pacemaker (CRT–P).

Response: We do not agree that it is necessary, as one commenter suggested, to establish a payment reduction limit for APC 0225, or any other device-dependent APC, until we have developed a methodology for device-dependent ratesetting that can incorporate data from multiple procedure claims. For all OPPS services, we continue our efforts to use the data from as many multiple procedure claims as possible, through approaches such as use of the bypass list and date splitting of claims as described further in section II.A. of this final rule with comment period, and through methodologies such as increased packaging and composite APCs. We believe that the standard device-dependent APC ratesetting methodology currently provides the most appropriate median costs for device-dependent APCs in which the hospital incurs the full cost of the device. As we discuss above in this section, we believe that decreases in the median costs for APC 0225 and other device-dependent APCs involving lead/electrode implantation are appropriate and attributable to the correction of inaccurate and incomplete hospital billing practices. However, we recognize the importance of maximizing our utilization of claims data, especially of claims that reflect common clinical scenarios, and that the number of single procedure claims available for ratesetting for many device-dependent APCs comprise a very low proportion of total bills for procedures that map to those APCs. We will continue to examine ways to utilize more claims data to set payment rates under the OPPS, including payment rates for device-dependent APCs, and appreciate the commenters' thoughtful suggestions. We refer readers to section II.A.2.e. of this final rule with comment period for a detailed summary of the public comments related to the establishment of a composite payment methodology for procedures involving CRT–D and CRT–P devices and our responses.

Comment: Several commenters requested that CMS alter the standard device-dependent APC ratesetting methodology in order to utilize data from multiple procedure claims for APC 0222 (Level II Implantation of Neurostimulator). They noted that, for CY 2008, CMS reconfigured the APC assignments for implantable neurostimulators to accommodate the inclusion of procedures involving both nonrechargeable and rechargeable neurostimulators (the pass-through status for which expired in CY 2007) and improve resource homogeneity among the neurostimulator APCs. The commenters further noted that the revised configuration provides payment for procedures involving mostly nonrechargeable neurostimulator technology (that is, cranial, sacral, gastric, or other peripheral neurostimulators) through two APCs—APC 0039 (Level I Implantation of Neurostimulator) and APC 0315 (Level III Implantation of Neurostimulator)—while establishing a single APC, APC 0222, for spinal neurostimulator implantation, which commonly utilizes either rechargeable or nonrechargeable technologies. The commenters summarized CMS' assessment in the CY 2008 OPPS/ASC final rule with comment period that, to the extent rechargeable spinal neurostimulators become the dominant device implanted in procedures described by the only CPT code assigned to APC 0222, CPT code 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling), the median cost for APC 0222 may increase to reflect contemporary utilization patterns.

The commenters raised concerns that analyses of the CY 2007 claims data demonstrate that the evolution to rechargeable spinal neurostimulators, while occurring in clinical practice and seen in the total billed claims, is not well represented in single procedure claims used for ratesetting for APC 0222. As a result, the commenters stated, the use of single procedure claims in the calculation of the median costs for APC 0222 systematically underestimates the use and cost of rechargeable neurostimulators. According to the data provided by the commenters, rechargeable neurostimulators are present on only 40 to 43 percent of single procedure claims, as opposed to 57 to 60 percent of all claims (both single and multiple procedure) for APC 0222. If CMS were to replace the device cost estimated for single procedure claims with the device cost estimated for total claims, the commenters stated, the median cost for APC 0222 would increase by 7 percent.

One commenter also contended that the median line-item device cost for neurostimulator generators was 17 percent lower in ''pure single claims'' when compared to all claims assigned to APC 0222. Another commenter noted that neurostimulator implantation procedures are reported with two separately payable CPT codes and consequently almost always appear on multiple procedure claims. The commenter argued that the single procedure claims used in ratesetting are either replacement procedures or incorrectly coded claims and do not reflect clinical practice in terms of either procedural frequency or cost.

Several commenters recommended that CMS calculate the payment rate for APC 0222 using the median device cost for rechargeable and nonrechargeable neurostimulators from all claims and the median procedure cost for CPT code 63685 from single procedure claims, arguing that larger claim samples lead to more accurate payment rates. The commenters stated that this would be an extension of CMS' process of using ''pseudo'' single procedure claims to calculate median costs, and would be consistent with CMS' focus on converting multiple procedure claims to ''pseudo'' single procedure claims in order to maximize the use of claims data in calculating median costs for OPPS ratesetting. According to the commenters, this approach would result in a 7 percent increase in the median cost for APC 0222 compared to the median cost calculated for the CY 2009 OPPS/ASC proposed rule.

Another commenter expressed the same concern that rechargeable neurostimulator costs were underrepresented in the claims data used to establish the median cost for APC 0222 and urged CMS to split APC 0222 into separate APCs based on whether a rechargeable or nonrechargeable spinal neurostimulator generator is utilized. Alternatively, the commenter asked CMS to consider a ratesetting methodology that, similar to the method offered by other commenters, would incorporate data from single and multiple procedure claims and result in a 9-percent increase in the median cost for APC 0222.

Response: We do not believe it is necessary or appropriate to alter our ratesetting methodology for device-dependent APC 0222. We believe that the revised neurostimulator APC configuration adopted in CY 2008, and our standard device-dependent APC ratesetting methodology, allow us to calculate appropriate OPPS payment rates for procedures involving spinal neurostimulators. The foundation of a system of relative weights is the relativity of the costs of all services to one another, as derived from a standardized system that uses standardized inputs and a consistent methodology. Adoption of a ratesetting methodology for APC 0222 that is different from our standard device-dependent APC ratesetting would undermine this relativity. A policy to provide different payments for the same procedures according to the types of devices implanted also would not be consistent with our overall strategy under the OPPS to encourage hospitals to use resources more efficiently by increasing the size of the payment bundles, as we described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66715 through 66716).

According to information provided by certain manufacturers of rechargeable neurostimulators in response to the CY 2008 OPPS/ASC final rule with comment period, rechargeable neurostimulators are clinically indicated in only a subset of patients for whom spinal neurostimulation is a treatment option. These manufacturers estimated that approximately 35 percent of these patients are candidates for rechargeable spinal neurostimulators, although this proportion may be higher (72 FR 66715). We note that, according to the data analysis submitted by the commenters, rechargeable neurostimulators were used in 40 to 43 percent of spinal neurostimulator implantation procedures included on single procedure claims for APC 0222 in CY 2007, and in 57 to 60 percent of spinal neurostimulator implantation procedures included on all claims (both single and multiple procedure) for APC 0222 in CY 2007. Therefore, the rate of implantation of rechargeable neurostimulators in Medicare beneficiaries in CY 2007 in the hospital outpatient setting appears to have met or exceeded the expectations of certain manufacturers that were expressed in their comments to the CY 2008 OPPS/ASC final rule with comment period. Based on these reported analyses, rechargeable neurostimulator technology appears to have been widely adopted into medical practice, and we expect that our CY 2009 OPPS payment rates will provide continued access to this technology for those patients for whom rechargeable neurostimulators are clinically indicated.

Comment: Several commenters stated that the proposed national unadjusted CY 2009 OPPS payment rate for cochlear implantation is significantly less than the average cost for the hospital to acquire the cochlear device and the associated costs to provide the implantation procedure and may impede patient access to this technology. The cochlear device implantation procedure is described by CPT code 69930 (Cochlear device implantation, with or without mastoidectomy), the only CPT code assigned to APC 0259 (Level VII ENT Procedures). The commenters remarked that, although the proposed CY 2009 OPPS payment rate is higher than the CY 2008 OPPS payment rate, it is also less than the OPPS national unadjusted CY 2007 OPPS payment rate, and occurs at a time when device costs and related hospital costs continue to rise. Some commenters stated that the true cost of the cochlear implant procedure, including the device and related surgical costs, is between $35,000 and $40,000, depending on the specific devices and services required for a given patient, while other commenters indicated that the cost to hospitals is approximately $32,000. Several commenters recommended that CMS adjust the median cost upon which the OPPS payment rate for APC 0259 is based by substituting a weighted average selling price of $24,500 for the median device cost from the CY 2007 OPPS claims of $18,420, where this selling price was calculated based on hospital invoice data supplied separately by the two leading cochlear implant manufacturers. The commenters indicated that this methodology would result in a median cost for APC 0259 of $30,037. Other commenters referenced a 2006 analysis, which found the average cost of cochlear implant procedures to be approximately $33,364, and asked that CMS reconsider establishing payment based on this figure.

The commenters also expressed concern about the proposed assignment and payment rate of procedures involving auditory osseointegrated devices, the pass-through status for which will expire on December 31, 2008. The commenters noted that CMS proposed in the CY 2009 OPPS/ASC proposed rule to package payment for these devices, described by HCPCS code L8690 (Auditory osseointegrated device, includes all internal and external components), into payment for their associated implantation procedures, described by CPT codes 69714 (Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy); 69715 (Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear

stimulator; with mastoidectomy); 69717 (Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy); and 69718 (Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy). Citing the CMS proposal to assign these implantation procedures to APC 0425 (Level II Arthroplasty or Implantation with Prosthesis) for CY 2009, the commenters stated that the proposed payment rate for APC 0425 would be insufficient to guarantee continued patient access to auditory osseointegrated devices and argued that the appropriate payment for procedures involving these devices should at least approximate the sum of the CY 2008 OPPS payment rate for APC 0256 (Level VI ENT Procedures), the APC to which the auditory osseointegrated device implantation procedures were assigned in CY 2007, and the average sales price for auditory osseointegrated devices, which they report totals $8,826 ($2,539 for APC 0256 plus $6,287 for device costs). The commenters also remarked that auditory osseointegrated device implantation procedures are clinically dissimilar to the other procedures assigned to APC 0425 and recommended that CMS establish a new APC for procedures involving osseointegrated devices. According to the commenters, APC 0425 is an inappropriate APC assignment for osseointegrated device implantation procedures because it is comprised of less device-intensive orthopedic procedures for the restoration of joint functioning. The commenters also stated that a training and audit process for the billing offices of hospitals performing osseointegrated device implantation procedures revealed widespread billing and coding errors, and indicated that these billing errors may contribute to a median cost calculation for osseointegrated device implantation procedures that is too low.

Response: We disagree with the commenters that it would be appropriate to use external pricing information in place of the costs derived from the claims and Medicare cost report data for APC 0259 or APC 0425 because we believe that to do so would distort the relativity that is so fundamental to the integrity of the OPPS. We have not systematically used external data to validate the median costs derived from claims data because external data lack relativity to the estimated costs derived from the claims and cost report data and generally are not appropriate for determining relative weights that result in payment rates. As described earlier in this section and in previous final rules such as the CY 2008 OPPS/ASC final rule with comment period (72 FR 66742), the foundation of a system of relative weights is the relativity of the costs of all services to one another, as derived from a standardized system that uses standardized inputs and a consistent methodology.

We also do not agree that auditory osseointegrated device implantation procedures are so clinically dissimilar to the other procedures assigned to APC 0425 that their assignment to that APC is not warranted. All procedures assigned to APC 0425 involve the implantation of a prosthestic device into bone. In regard to the commenters' concerns that billing and coding errors may have contributed to an inaccurate median cost calculation for APC 0425, we note that, because APC 0425 is a device-dependent APC, we calculated the median cost for osseointegrated device implantation procedures using only correctly coded claims that included the HCPCS device code for the osseointegrated device, L8690, along with an appropriate procedure code. Effective January 1, 2009, we also will implement procedure-to-device edits that require all hospitals paid under the OPPS to report HCPCS code L8690 whenever they report an osseointegrated device implantation procedure described by CPT codes 69714, 69715, 69717, and 69718. We also will implement the appropriate device-to-procedure edits to ensure that when HCPCS code L8690 is reported, an appropriate implantation procedure code is also included on the claim.

Comment: One commenter accepted CMS' consistent reliance on claims data to establish the CY 2009 OPPS/ASC proposed rule median cost for CPT code 36566 of $2,092, but disagreed with the proposed reassignment of CPT code 36566 to APC 0623 and urged CMS to maintain APC 0625. While the median cost for CPT code 36566 is very similar to the median costs of other procedures assigned to APC 0623, the commenter stated that the amounts will likely diverge in the future.

Response: We do not believe it would be appropriate to maintain an APC that is not necessary to classify services into groups that are similar clinically and in terms of resource utilization based on purported anticipated future costs. We continue to believe that CPT code 36566 is most appropriately assigned to APC 0623 for CY 2009, as we proposed, based on consideration of the procedure's clinical and resource characteristics. We reassess the composition of APCs, including reviewing the median costs of individual HCPCS codes, annually when we have new claims and Medicare cost report data and propose those changes through our annual rulemaking cycle that we believe are necessary to maintain the clinical and resource homogeneity of APCs based on that updated data. To the extent that the median cost of CPT code 36566 changes significantly in the future, we may propose future changes to the CPT code's assignment if we determine that a different APC would be more appropriate.

After consideration of the public comments received, we are finalizing our proposed CY 2009 payment policies for device-dependent APCs, with modification to reassign CPT code 64553 from APC 0225 to APC 0040. The CY 2009 OPPS payment rates for device-dependent APCs are based on their median costs calculated from CY 2007 claims and the most recent cost report data, using only claims that pass the device edits, do not contain token charges for devices, and do not have a modifier signifying that the device was furnished without cost or with full credit. We continue to believe that the median costs calculated from the single bills that meet these three criteria represent the most valid estimated relative costs of these services to hospitals when they incur the full cost of the devices required to perform the procedures. The CY 2009 device-dependent APCs are listed in Table 3 below.

TABLE 3—CY 2009 DEVICE-DEPENDENT APCS

Final CY 2009 APC	Final CY 2009 status indicator	CY 2009 APC title
0039	S	Level I Implantation of Neurostimulator.
0040	S	Percutaneous Implantation of Neurostimulator Electrodes.

TABLE 3—CY 2009 DEVICE-DEPENDENT APCS—Continued

Final CY 2009 APC	Final CY 2009 status indicator	CY 2009 APC title
0061	S	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes.
0082	T	Coronary or Non Coronary Atherectomy.
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.
0222	S	Level II Implantation of Neurostimulator.
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 III Implantation of Neurostimulator.
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 Elect.
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.
0681	T	Knee Arthroplasty.

(2) Blood and Blood Products

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

In the CY 2009 OPPS/ASC proposed rule (73 FR 41439), we proposed to continue to establish payment rates for blood and blood products for CY 2009 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 difference in CCRs and to better reflect hospitals' costs, we proposed to continue to simulate blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers. We would then apply this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports in order to simulate blood-specific CCRs for those hospitals. We calculated the median costs upon which the proposed CY 2009 payment rates for blood and blood products were based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific simulated blood-specific CCR for hospitals that did not report costs and charges for a blood cost center. 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).

As we indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41439), we believe that the 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 2009 will 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 products in general.

As discussed in section XIII.A.1. of this final rule with comment period, we also proposed to create status indicator ''R'' (Blood and Blood Products) to denote blood and blood products for publication and payment purposes in CY 2009. We believe that it is necessary to create a status indicator that is specific to blood and blood products to facilitate development of blood product median costs under the blood-specific CCR methodology and to facilitate implementation of the reduced payments that will be made to hospitals that fail to report the hospital outpatient quality data, as discussed in section XVI.D.2. of this final rule with comment period.

Comment: One commenter remarked that the proposed blood-specific CCR methodology accurately reflects the relative estimated costs of blood and blood products for hospitals without blood cost centers and for these products in general. The commenter encouraged CMS to continue the historical practice of providing separate payments for blood and blood products through APCs, rather than packaging their payment into payments for the procedures with which they are administered. Another commenter stated that the proposed payment rates for many blood and blood products are less than the actual acquisition costs, particularly for high volume blood products. The commenter noted that the proposed payment rate for the most commonly transfused blood product, leukocyte-reduced red blood cells described by HCPCS code P9016 (Red blood cells, leukocytes reduced, each unit), is less than hospitals' average acquisition cost for the product (not including overhead, storage, handling, and wastage) according to a nationwide survey of 2006 blood costs. The survey was conducted by the American Association of Blood Banks under a contract with HHS and includes data from approximately 1,700 hospitals. The commenter noted that since 2006, the year for which cost data were collected, the costs of acquiring blood products have continued to increase due to new safety advances and increasingly expensive donor recruitment and retention efforts. The commenter recommended that CMS continue to increase payments for blood products, particularly leukocyte-reduced red blood cells, to bridge the perceived gap between Medicare payments and the actual costs incurred by hospitals.

Response: We continue to believe that using blood-specific CCRs applied to hospital claims data results in payments that appropriately reflect hospitals' relative costs of providing blood and blood products as reported to us by hospitals. We do not believe it is necessary or appropriate to incorporate external survey data into our ratesetting process for blood and blood products because, in a relative weight system, it is the relativity of the costs to one another, rather than absolute cost, that is most important for setting payment rates. External data lack relativity to the estimated costs derived from the claims and cost report data and generally are not appropriate for determining relative weights that result in payment rates. We note that median costs per unit (calculated using the blood-specific CCR methodology) for this final rule with comment period increase from CY 2008 for 16 of the top 20 highest volume blood products.

Comment: One commenter asked that CMS reconsider the proposed payment rate of approximately $30 for HCPCS code P9011 (Blood, split unit), indicating that this payment rate was much lower than the CY 2008 payment rate of approximately $149 and would fail to cover the costs of split units of blood. The commenter also was concerned that the proposed payment decrease would result in insufficient Medicaid payment for transfusions involving split blood products.

Response: We do not agree that it would be appropriate to deviate from our standard methodology of using blood-specific CCRs to calculate the median cost upon which payment is based for HCPCS code P9011, despite the significant decrease in median cost from the CY 2006 claims data used for ratesetting in CY 2008 relative to the CY 2007 claims data used for ratesetting in CY 2009. We believe that some variation in relative costs from year to year is to be expected in a prospective payment system, particularly for low volume items such as HCPCS code P9011. We also note that, because HCPCS code P9011 is defined only as a split unit of blood and no particular designation is made within the code's descriptor as to the type or volume of blood product that makes up the split unit reported, the median cost for this HCPCS code also may vary based upon the types and volumes of split products hospitals report using HCPCS code P9011.

Public comments on Medicaid payment for blood and blood products are not within the scope of this CY 2009 OPPS/ASC final rule with comment period, as it is only within our purview to establish payment rates for HOPDs that receive payment under the OPPS for services furnished to Medicare beneficiaries.

We also note that it is our common practice to review significant changes in median costs from year to year and from the proposed rule to the final rule for a given calendar year. Although a handful of HCPCS codes experienced decreases in median cost for CY 2009 from the proposed rule to this final rule with comment period, most notably HCPCS codes P9011 and P9043 (Infusion, plasma protein fraction (human), 5%, 50ml), we determined that the decreases in median cost were due to contributions of additional claims and revised cost report data. For all APCs whose payment rates are based upon relative payment weights, we note that the quality and accuracy of reported units and charges significantly influence the final median costs that are the basis for our payment rates, especially for low volume items and services. Beyond our standard OPPS trimming methodology (described in section II.A.2. of this final rule with comment period) that we apply to those claims that have passed various types of claims processing edits, it is not our policy to judge the accuracy of hospital coding and charging for purposes of ratesetting.

After consideration of the public comments received, we are finalizing, without modification, our CY 2009 proposal to calculate the median costs upon which the CY 2009 payment rates for blood and blood products are based using the blood-specific CCR methodology that we have utilized since CY 2005. We continue to believe this methodology is the best mechanism to deal with the absence of a blood-specific CCR for hospitals that do not use the blood cost center. We believe that continuing with this methodology, which takes into account the unique charging and cost accounting structure of each provider, results in median costs for blood and blood products that appropriately reflect the relative estimated costs of these products. As discussed in section XIII.A.1. of this final rule with comment period, we also are finalizing our proposal to create status indicator ''R'' to denote blood and blood products in Addendum B to this final rule with comment period for publication and payment purposes.

(3) Single Allergy Tests

In the CY 2009 OPPS/ASC proposed rule (73 FR 41439 through 41440), we proposed 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 2009. 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 of these CPT codes to describe all of the tests provided. However, as noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41439), our CY 2007 claims data available for that rule for APC 0381 did not reflect improved and more consistent hospital billing practices of ''per test'' for single allergy tests. The median cost of APC 0381, calculated for the proposed rule according to the standard single claims OPPS methodology, was approximately $51, significantly higher than the CY 2008 median cost of APC 0381 of approximately $17 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 CYs 2006, 2007, and 2008, we calculated a proposed ''per unit'' median cost for APC 0381 of $25, based upon 520 claims containing multiple units or multiple occurrences of a single CPT code. For a full discussion of this methodology, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66737).

We did not receive any public comments on our CY 2009 proposal for payment of single allergy tests. Therefore, we are finalizing our CY 2009 proposal, without modification, to calculate a ''per unit'' median cost for APC 0381 as described above in this section. The final CY 2009 median cost of APC 0381 is approximately $23.

(4) Echocardiography Services

In the CY 2009 OPPS/ASC proposed rule (73 FR 41440), we proposed to continue the packaging of payment for all contrast agents into the payment for the associated imaging procedure for CY 2009, as we did in CY 2008. For echocardiography services, we proposed to estimate median costs using the same methodology that we used to set medians for these services for CY 2008. In CY 2008, we finalized a policy to package payment for all contrast agents into the payment for the associated imaging procedure, regardless of whether the contrast agent met the OPPS drug packaging threshold. Section 1833(t)(2)(G) of the Act requires us to create additional APC groups of services for procedures that use contrast agents that classify them separately from those procedures that do not utilize contrast agents. To reconcile this statutory provision with our final policy of packaging all contrast agents, for CY 2008, we calculated HCPCS code-specific median costs for all separately payable echocardiography procedures that may be performed with contrast agents by isolating single and ''pseudo'' single claims with the following CPT codes where a contrast agent was also billed on the claim: 93303 (Transthoracic echocardiography for congenital cardiac anomalies; complete); 93304 (Transthoracic echocardiography for congenital cardiac anomalies; follow-up or limited study); 93307 (Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete); 93308 (Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; follow-up or limited study); 93312 (Echocardiography, transesophageal, real time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report); 93315 (Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report); 93318 (Echocardiography, transesophageal (TEE) for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis); and 93350 (Echocardiography, transthoracic, real-time with image documentation (2D), with or without M-mode recording, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report). As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66644), our analysis indicated that all echocardiography procedures that may be performed with contrast agents are reasonably similar both clinically and in terms of resource use, as evidenced by similar HCPCS code-specific median costs.

As provided for under the statute, for CY 2008, we created APC 0128 (Echocardiogram With Contrast) to provide payment for echocardiography procedures that are performed with a contrast agent. In addition, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66644 through 66646), in order for hospitals to identify separately and receive appropriate payment for echocardiography procedures performed with contrast beginning in CY 2008, we created eight new HCPCS codes (C8921 through C8928) that corresponded to the related CPT echocardiography codes and assigned them to the newly created APC 0128. We instructed hospitals performing echocardiography procedures without contrast to continue to report the CPT codes and to report the new HCPCS C-codes when performing echocardiography procedures with contrast or without contrast followed by with contrast.

As noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41440), claims data from CY 2008 are not yet available for ratesetting, so we do not yet have claims data specific to HCPCS codes C8921 through C8928 in order to determine the CY 2009 payment rate for APC 0128. Therefore, for CY 2009, we proposed to again use the methodology that we used to set the CY 2008 payment rate for APC 0128 (72 FR 66645). That is, we isolated single and ''pseudo'' single claims in our database that included those CPT codes in the range of 93303 through 93350 as described above in this section that correspond to the contrast studies described by HCPCS codes C8921 through C8928. For claims where one of these echocardiography procedures was billed with a contrast agent, we packaged the cost of the contrast agent into the cost of the echocardiography procedure and then calculated a median cost for APC 0128 using this subset of claims. As in CY 2008, the HCPCS code-specific median costs for echocardiography procedures performed with contrast are all similar, and we continue to believe these services share sufficient similarity to be assigned to the same APC.

For CY 2009, we also recalculated the median cost for APCs 0269 (Level II Echocardiogram Without Contrast

Except Transesophageal); 0270 (Transesophageal Echocardiogram Without Contrast); and 0697 (Level I Echocardiogram Without Contrast Except Transesophageal), as we did in CY 2008 (72 FR 66645). We used claims for CPT codes 93303 through 93350 after removing claims from the ratesetting process that included contrast agents because these claims were used to set the median cost for APC 0128.

Comment: One commenter noted that a new CPT code will be available in CY 2009 that combines spectral and color Doppler with transthoracic echocardiography. The commenter stated that hospitals using this code in CY 2009 will be able to assign costs to this new code, but expressed concern as to how CMS plans to provide payment for the years before claims data are available.

Response: Typically, our process for providing payment for CPT codes that are newly recognized under the OPPS for payment in the upcoming calendar year is to provide interim APC assignments in the final rule with comment period for that upcoming year. The APC assignment of these codes is then open to comment on that final rule. We note that there are circumstances regarding the new CPT code referenced by the commenter, CPT 93306 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography), that contributed to our CY 2009 interim APC assignment for that code. There were also several factors that contributed to our decision regarding the final APC assignment for CPT code 93307 for CY 2009.

First, as discussed above in this section, in CY 2008, we implemented HCPCS C-codes for hospitals to identify echocardiography procedures provided with contrast, or without contrast followed by with contrast. As these data are not yet available for ratesetting for CY 2009, we used the same process for CY 2009 as we did for CY 2008 to separately identify echocardiography services provided with contrast and those provided without contrast.

Second, the American Medical Association (AMA) revised several CPT codes in the 93000 series to more specifically describe particular services provided during echocardiography procedures. The CY 2009 descriptor for CPT code 93306 essentially includes the services described in CY 2008 by CPT codes 93307 (Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete); 93320 (Doppler echocardiography, pulsed wave and/or continuous wave with spectral display; complete) and 93325 (Doppler echocardiography color flow velocity mapping). Therefore, in CY 2008, the service described in CY 2009 by new CPT code 93306 is reported with three CPT codes, specifically CPT codes 93307, 93320, and 93325, and the hospital receives separate payment for CPT code 93307 through APC 0269, into which payment for the other two services is packaged. The revised CY 2009 descriptor of CPT code 93307 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography) explicitly excludes services described by CPT codes 93320 and 93325.

To determine the hospital costs of CPT codes 93306 and 93307 under CY 2009 definitions for purposes of CY 2009 ratesetting, we redefined our CY 2007 single and ''pseudo'' single claims. We began by redefining the single claims for CPT code 93307 billed with packaged CPT codes 93320 and 93325 as single claims for CPT code 93306. We identified almost 600,000 CY 2007 single and ''pseudo'' single claims for CPT code 93306. We then limited the single claims for CPT code 93307 to reflect the newly revised descriptor for CY 2009, that is, those claims where CPT code 93307 was not billed with either packaged CPT code 93320 or CPT code 93325. We identified roughly 13,000 single and ''pseudo'' single claims for revised CPT code 93307.

Having created claims that reflected CY 2009 definitions, we then followed our proposed CY 2009 methodology for calculating HCPCS code-specific median costs for these echocardiography procedures with and without contrast by dividing the new set of single and ''pseudo'' single claims for CPT codes 93306 and 93307 into those billed without and with contrast agents. We first calculated a HCPCS code-specific median cost for new CPT code 93306 when it was billed without contrast. We had over 500,000 claims that fit this criterion, and the median cost for this service was approximately $425. We then calculated a HCPCS code-specific median cost for CPT code 93307 under the newly revised descriptor for CY 2009 without contrast. We had approximately 13,000 claims that fit this criterion. The median cost for this service was approximately $256.

In addition, as discussed above in this section, in CY 2008, we began providing separate payment for echocardiography services that are performed with contrast through APC 0128. In accordance with this policy and the revised and new CPT codes, we calculated a HCPCS code-specific median cost for new CPT code 93306 using the set of redefined single claims billed with contrast. Over 9,000 claims met this criterion, and the median cost for CPT code 93306 with contrast was approximately $569. Consistent with our CY 2008 policy of providing HCPCS C-codes for billing the ''with contrast'' form of the echocardiography CPT code, we identified this set of claims to represent new HCPCS code C8929 (Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography).

Finally, we calculated a HCPCS code-specific median cost for CPT code 93307 using single claims for CPT code 93307 under the newly revised descriptor for CY 2009 when billed with contrast. We had 168 claims that fit this criterion, and the median cost for this service was approximately $376. We identified this set of claims to represent revised HCPCS code C8923 (Transthoracic echocardiography with contrast, or without contrast followed by with contrast, real-time with image documentation (2D), includes M-mode recording, when performed, complete, without spectral or color Doppler echocardiography). Based on their HCPCS code-specific median costs, we have assigned new CPT code 93306 (with a median cost of approximately $425 based on the methodology described above in this section) without contrast to APC 0269 for CY 2009 on an interim basis. In addition, we have reassigned CPT code 93307 without contrast, using the updated CPT descriptor and the criteria described above in this section to develop a median cost of approximately $256, to APC 0697 for CY 2009. We have assigned new HCPCS code C8929 on an interim basis and revised HCPCS code C8923 on a final basis to APC 0128. All codes with interim assignments are designated with comment indicator ''NI'' in Addendum B to this final rule with comment period, and their OPPS treatment is open to comment in this final rule with comment period.

Comment: One commenter disagreed with the proposed payment for fetal echocardiography services in general, while several other commenters suggested that the proposed assignment of CPT code 76825 (Echocardiography,

fetal, cardiovascular system, real time with image documentation (2D), with or without M-mode recording) to APC 0266 (Level II Diagnostic and Screening Ultrasound) and CPT code 76826 (Echocardiography, fetal, cardiovascular system, real time with image documentation (2D), with or without M-mode recording; follow-up or repeat study) to APC 0265 (Level I Diagnostic and Screening Ultrasound) did not provide an accurate representation of the resources required by these two CPT codes. These commenters noted that the resources required to perform these procedures differ substantially from the other services included in APCs 0265 and 0266 and that resource use exceeds that for comparable studies on adults. In addition, the commenters suggested that CMS reassign CPT code 76825 to APC 0269 and CPT code 76826 to APC 0697.

Response: We agree with the commenters that the services described by CPT codes 76825 and 76826 are most appropriately grouped with the services assigned to APCs 0269 and 0697, respectively. The resource use and clinical characteristics of these fetal echocardiography services resemble those of nonfetal echocardiography services also assigned to APCs 0269 and 0697 for CY 2009. Therefore, we are reassigning CPT code 76825 to APC 0269, and CPT code 76826 to APC 0697 for CY 2009. In reference to the general comment regarding fetal echocardiography services, we note that CPT codes 76827 (Doppler echocardiography, fetal, pulsed wave and/or continuous wave with spectral display; complete) and 76828 (Doppler echocardiography, fetal, pulsed wave and/or continuous wave with spectral display; follow-up or repeat study) are also included in this general service type. We have reviewed the proposed APC assignments of these two CPT codes, and we have concluded that the clinical characteristics of these services and their HCPCS code-specific median costs from hospital claims data (approximately $92 and $77, respectively) are similar to those of other services also assigned to APC 0265, which has a final CY 2009 APC median cost of approximately $61. Therefore, in the absence of specific recommendations to move these codes to another APC or other detailed information from commenters in support of their reassignment, we believe that CPT codes 76827 and 76828 are most appropriately assigned to APC 0265 for CY 2009, as we proposed.

Comment: One commenter agreed with our procedure regarding identifying those echocardiography procedures with and without contrast until the specific HCPCS C-code data are available for ratesetting purposes. However, the commenter expressed concern that because of low utilization of contrast for echocardiography procedures, the median cost for APC 0128 may not accurately reflect all of the resources required to provide contrast echocardiography services. The commenter suggested that CMS review those echocardiography procedures that are performed with contrast and consider creating more than one APC that includes echocardiography services performed with contrast.

Response: We have reviewed the HCPCS code-specific median costs for echocardiography services performed with contrast in our CY 2007 claims data, and we continue to believe that the median cost of APC 0128 accurately reflects the hospital costs of performing echocardiography procedures with contrast. We see no need, based on clinical characteristics or median costs as reflected in the hospital claims data, to develop another APC for certain echocardiography procedures with contrast. Only two services assigned to APC 0128 for CY 2009 are significant procedures, specifically with contrast studies described by CPT code 93306 (based on the subset of claims that met our criteria described above in this section) and CPT code 93350, with median costs of approximately $569 and $537, respectively. Other echocardiography services are rarely provided with contrast to Medicare beneficiaries. Furthermore, we believe that the final OPPS coding and payment methodology for echocardiography services allows us to both adhere to the statutory requirement to create additional groups of services for procedures that use contrast agents and to continue packaged payment for contrast agents.

After consideration of the public comments received, we are finalizing our CY 2009 payment proposals for echocardiography services, with modification to reassign CPT code 93307 to APC 0697 and to assign new CPT code 93306 to APC 0269 based on their revised and new CY 2009 CPT code descriptors, respectively. In addition, we are reassigning CPT code 76825 and CPT code 76826 for fetal echocardiography services to APC 0269 and APC 0697, respectively. The final echocardiography APCs and their CY 2009 median costs are listed in Table 4 below.

TABLE 4—CY 2009 ECHOCARDIOGRAPHY APCS

Final CY 2009 APC	CY 2009 APC title	Final CY 2009 approximate APC median cost
0128	Echocardiogram with Contrast	$553
0269	Level II Echocardiogram Without Contrast Except Transesophageal	422
0270	Transesophageal Echocardiogram Without Contrast	539
0697	Level I Echocardiogram Without Contrast Except Transesophageal	249

(5) Nuclear Medicine Services

In CY 2008, we began packaging payment for diagnostic radiopharmaceuticals into the payment for the associated nuclear medicine procedure. (For a discussion regarding the distinction between diagnostic and therapeutic radiopharmaceuticals, we refer readers to the CY 2008 OPPS/ASC final rule at 72 FR 66636.) Prior to the implementation of this policy, diagnostic radiopharmaceuticals were subject to the standard OPPS drug packaging methodology whereby payments are packaged when the estimated mean per day product costs fall at or below the annual packaging threshold for drugs, biologicals, and radiopharmaceuticals.

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 supportive items and services into the payment for the independent procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility. All nuclear medicine

procedures require the use of at least one radiopharmaceutical or other radiolabeled product, and there are only a small number of radiopharmaceuticals that may be appropriately billed with each diagnostic nuclear medicine procedure. For the OPPS, we distinguish diagnostic radiopharmaceuticals from therapeutic radiopharmaceuticals for payment purposes, and this distinction is recognized in the Level II HCPCS codes for diagnostic radiopharmaceuticals that include the term ''diagnostic'' along with a radiopharmaceutical in their HCPCS code descriptors. As we stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66635), we believe that our policy to package payment for diagnostic radiopharmaceuticals (other than those already packaged when their per day costs are below the packaging threshold for OPPS drugs, biologicals, and radiopharmaceuticals) is consistent with OPPS packaging principles, provides greater administrative simplicity for hospitals, and encourages hospitals to use the most clinically appropriate and cost efficient diagnostic radiopharmaceutical for each study. For more background on this policy, we refer readers to discussions in the CY 2008 OPPS/ASC proposed rule (72 FR 42667 through 42672) and the CY 2008 OPPS/ASC final rule with comment period (72 FR 66635 through 66641).

For CY 2008 ratesetting, we used only claims for nuclear medicine procedures that contained a diagnostic radiopharmaceutical in calculating the median costs for APCs including nuclear medicine procedures (72 FR 66639). This is similar to the established methodology used for device-dependent APCs before claims reflecting the procedure-to-device edits were included in our claims data. For CY 2008, we also implemented claims processing edits (called procedure-to-radiolabeled product edits) requiring the presence of a radiopharmaceutical (or other radiolabeled product) HCPCS code when a separately payable nuclear medicine procedure is present on a claim. Similar to our practice regarding the procedure-to-device edits that have been in place for some time, we continually review comments and requests for changes related to these edits and, based on our review, may update the edit list during our quarterly update process if necessary. The radiopharmaceutical (and other radiolabeled product) and procedure HCPCS codes that are included in these edits can be viewed on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/01_overview.asp*.

The CY 2008 OPPS claims that are subject to the procedure-to-radiolabeled product edits will not be available for setting payment rates until CY 2010 and, therefore, are not yet available to set payment rates for CY 2009. Therefore, in the CY 2009 OPPS/ASC proposed rule (73 FR 41440), we proposed to continue our established CY 2008 methodology for setting the payment rates for APCs that include nuclear medicine procedures for CY 2009. We used an updated list of radiolabeled products, including but not limited to diagnostic radiopharmaceuticals, from the procedure-to-radiolabeled product edit file to identify single and ''pseudo'' single claims for nuclear medicine procedures that also included at least one eligible radiolabeled product. Using this subset of claims, we followed our standard OPPS ratesetting methodology, discussed in section II.A. of this final rule with comment period, to calculate median costs for nuclear medicine procedures and their associated APCs.

We identified those APCs containing nuclear medicine procedures that would be subject to this methodology under our CY 2009 proposal in Table 4 of the CY 2009 OPPS/ASC proposed rule, and shown below in Table 5. As in CY 2008, when we set APC median costs based on single and ''pseudo'' single claims that also included at least one radiolabeled product on our edit file, we observed an equivalent or higher median cost than that calculated from all single and ''pseudo'' single bills. We believe that this methodology appropriately ensures that the costs of diagnostic radiopharmaceuticals are included in the ratesetting process for these APCs.

During its March 2008 meeting, the APC Panel recommended that CMS continue to package payment for diagnostic radiopharmaceuticals for CY 2009. In addition, the APC Panel recommended that CMS present data at the first CY 2009 APC Panel meeting on usage and frequency, geographic distribution, and size and type of hospitals performing nuclear medicine studies using radioisotopes in order to ensure that access to diagnostic radiopharmaceuticals is preserved for Medicare beneficiaries. We discuss, below, our response to these APC Panel recommendations along with our response to public comments.

Comment: A number of the commenters opposed CMS' proposed policy to package payment for all diagnostic radiopharmaceuticals into their associated nuclear medicine procedure. They noted that the majority of diagnostic radiopharmaceuticals are not interchangeable, and for that reason, the CMS policy of packaging all diagnostic radiopharmaceuticals into their associated nuclear medicine procedure does not foster hospital efficiencies. Some of these commenters expressed concern that packaging diagnostic radiopharmaceuticals into the payment for associated nuclear medicine procedures results in overpayment of many procedures, especially those using existing lower-cost radiopharmaceuticals, while the bundled payment would be insufficient for newer, and likely more expensive, radiopharmaceuticals.

In addition, the commenters requested that if CMS continues to package payment for diagnostic radiopharmaceuticals into payment for their associated nuclear medicine procedures, CMS should revise the nuclear medicine APCs to provide differential payments for nuclear medicine procedures when used with different radiopharmaceuticals. Several commenters identified the series of tumor/infection imaging APCs, including APCs 0406 (Level I Tumor/Infection Imaging), 0408 (Level III Tumor/Infection Imaging), and 0414 (Level II Tumor/Infection Imaging), for CMS' attention to ensure appropriate payment for low volume, high cost radiopharmaceuticals. One commenter specifically suggested a composite APC for specific combinations of a tumor imaging scan and certain diagnostic radiopharmaceuticals. Several commenters noted that there is wide variation in the costs of diagnostic radiopharmaceuticals, and that composite APCs for specific combinations of procedures and diagnostic radiopharmaceuticals would be necessary to ensure adequate payment to hospitals using expensive diagnostic radiopharmaceuticals. Other commenters suggested that the significant clinical and resource diversity of radiopharmaceuticals packaged into nuclear imaging procedures amounted to a violation of the 2 times rule. The commenters explained that just as diagnostic radiopharmaceuticals are not interchangeable, certain radiopharmaceuticals are indicated for particular types of diseases, such as cancer, and are not clinically similar to other radiopharmaceuticals used for other purposes, such as tumor imaging.

Response: We understand that the selection of a diagnostic radiopharmaceutical for a particular nuclear medicine procedure is a complex decision based on many factors, including patient-specific

factors, and that not every diagnostic radiopharmaceutical is fully interchangeable with others. However, as stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66617), we believe that nonspecific packaging (as opposed to selected code packaging) based on combinations of items and services observed on hospital claims is fully appropriate because of the myriad combinations of items and services that can be appropriately provided together. Under the OPPS, we package payment for ancillary, supportive, and interrelated items and services into payment for the independent services they accompany. As we discuss in section II.A.4. of this final rule with comment period, packaging promotes hospital efficiencies through numerous means, not only just through the choice of which radiopharmaceutical to use for a specific nuclear medicine scan. While all diagnostic radiopharmaceuticals may not be interchangeable, we believe that packaging the costs of diagnostic radiopharmaceuticals, however differential those costs may be, into the payment for nuclear medicine services that use these products is appropriate, whether there is one product or multiple products that could be used to furnish the particular service provided to an individual patient. The OPPS has a history of packaging items that are not necessarily interchangeable. It is our longstanding practice to package payment for nonpass-through implantable medical devices into payment for the procedure in which they are used, notwithstanding that there may be different devices or combinations of devices that could be used to furnish a service. (For a more complete discussion of the history of packaging items, we refer readers to the CY 2008 OPPS/ASC final rule with comment period at 72 FR 66639.) Therefore, in combination with our understanding that a diagnostic radiopharmaceutical is never provided without an accompanying nuclear medicine scan, we believe that it is appropriate to package the payment for all diagnostic radiopharmaceuticals into the payment for the associated nuclear medicine procedure.

With regard to suggested composites or other revisions designed to isolate specific nuclear medicine scans with a subset of diagnostic radiopharmaceuticals, we do not believe that the inability to substitute one diagnostic radiopharmaceutical for another is a compelling reason for creating composite APCs, as explained below. We developed composite APCs to provide a single payment for two or more services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Composite APCs differ from packaging. Composite APCs provide a single payment for specific combinations of independent services that would otherwise be separately payable if they were not provided together, while packaging entails associating the cost of ancillary, supportive, and interrelated services and supplies with a distinct service or composite service. Composite APCs are intended to expand the OPPS payment bundles to encourage hospital efficiencies. Providing a single payment for a specific combination of a diagnostic radiopharmaceutical with a particular nuclear medicine procedure would not constitute a composite APC and would provide no incentives for hospital efficiency. From the perspective of value-based purchasing, we see no benefit to paying for many individual diagnostic radiopharmaceutical and nuclear medicine procedure combinations over paying separately for both the item and service, beyond an appearance of bundling. Such an approach would add complexity to ratesetting and would create challenges and cost instability because payments would be based on data from small numbers of claims for certain HCPCS code pairs. As noted above, there are many items and services that we package under the OPPS that are similarly not interchangeable with other related items and services.

We understand that by packaging payment for a range of products such as diagnostic radiopharmaceuticals, payment for the associated nuclear medicine procedure may be more or less than the hospital's cost for these services in a given case. As stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66639), we note that the most fundamental characteristic of a prospective payment system is that payment is to be set at an average for the service, which, by definition, means that some services are paid more or less than average. As explained above in this section, in order to more accurately account for these packaged services, for CY 2009 ratesetting, we used only correctly coded claims for nuclear medicine procedures that contained a radiolabeled product in calculating the CY 2009 median costs for APCs including nuclear medicine procedures.

We discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66640) the issue of variability in radiopharmaceutical costs or other packaged costs creating potential 2 times violations. We note that 2 times violations are specific to the total cost of the primary service, nuclear medicine scans in this case, including packaged costs. We have performed our standard review of the APCs using updated CY 2007 claims data for this final rule with comment period and, as a result, have not identified any 2 times violations in the APCs containing nuclear medicine procedures, when calculated as described above. (For more information on the 2 times rule, we refer readers to sections III.B.2. and 3. of this final rule with comment period.)

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to set the payment rates for APCs containing nuclear medicine procedures based on those claims that also contain a radiolabeled product to ensure that the costs of diagnostic radiopharmaceuticals are appropriately packaged into the costs of nuclear medicine procedures. The CY 2009 APCs to which nuclear medicine procedures are assigned and for which we required radiolabeled products on the nuclear medicine procedure claims used for ratesetting are displayed in Table 5 below.

Comment: Several commenters cited concerns regarding the proposed APC assignments and proposed payment rates for a number of the nuclear medicine procedures. These commenters noted that the APC assignments of certain nuclear medicine procedures led to clinically diverse procedures being grouped together for payment purposes. Furthermore, they added that, in some cases, nuclear medicine procedures with very different resource requirements, such as positron emission tomography (PET) and PET/computed tomography (CT) scans, were grouped together.

Specifically, one commenter requested that (1) CPT code 78645 (Cerebrospinal fluid flow, imaging (not including introduction of material); shunt evaluation) be reassigned from APC 0403 (Level I Nervous System Imaging) to APC 0402 (Level II Nervous System Imaging); (2) CPT code 78608 (Brain imaging, positron emission tomography (PET); metabolic evaluation) be reassigned from APC 0308 (Non-Myocardial Positron Emission Tomography (PET) Imaging) to a more appropriate APC; and (3) CPT codes 78000 (Thyroid uptake; single determination) and 78001 (Thyroid uptake; multiple determinations) be reassigned from APC 0389 (Level I Non-imaging Nuclear Medicine) to APC 0392

(Level II Non-imaging Nuclear Medicine).

Response: We have performed our annual review of all the procedures and APC groupings for this final rule with comment period based on updated CY 2007 claims data. The HCPCS code-specific median cost of CPT code 78645 is approximately $208 based on 425 single claims, which is reasonably close to the median cost of APC 0403 of approximately $182, where we proposed to assign the service. The commenter recommended assignment of CPT code 78645 to APC 0402, in the same nervous system imaging series, with an APC median cost of approximately $536. Based on this review of costs, we continue to believe CPT code 78645 is most appropriately assigned to APC 0403 as we proposed, as the HCPCS code-specific median cost of CPT code 78645 is more comparable to the level of hospital resources that are reflected in the median cost of APC 0403 than the level of resources reflected in the median cost of APC 0402.

There is a single APC for nonmyocardial PET scans, APC 0308, with a median cost of approximately $1,014. The median costs of all CPT codes assigned to that APC, including CPT codes for PET scans and PET/CT scans and CPT code 78608 for a metabolic evaluation of the brain using PET, range from approximately $891 to $1,164, demonstrating very significant resource similarity. Therefore, we do not agree with commenters that the proposed configuration of APC 0308 should be modified because all of these nonmyocardial services that use PET technology demonstrate very similar costs and share clinical similarity as well.

With regard to the thyroid scans described by CPT codes 78000 and 78001, these procedures have HCPCS code-specific median costs of approximately $109 and $117, respectively, very close to the median cost of APC 0389 of approximately $115, where we proposed to assign them. There is only one other service, with one single claim, assigned to APC 0389, other than an unlisted code whose data do not contribute to ratesetting for the APC. Therefore, these two CPT codes determine the median cost of APC 0389. In contrast, the median cost of APC 0392, their recommended placement according to the commenter, is approximately $161, substantially greater than the median costs of the two thyroid studies. Therefore, we do not believe any changes to the proposed APC assignments of CPT codes 78000 or 78001 are justified.

Comment: Several commenters disagreed with the proposed payment rate for myocardial PET scan services because they believed that the payment rate is based on inadequate hospital data consisting of fewer than 2,800 claims. They stated that the CY 2009 proposed payment rate of approximately $1,143 for myocardial PET scan services decreased 18 percent compared to the CY 2008 payment rate of approximately $1,400 for these services. The commenters believed that the proposed payment rate for APC 0307 (Myocardial Positron Emission Tomography (PET) Imaging) is substantially less than the cost of providing the services involved, including the use of a relatively costly diagnostic radiopharmaceutical. They urged CMS to accept external data in light of the limited hospital claims data in order to set the payment rate for myocardial PET scans. If external data are not used for CY 2009 ratesetting, the commenters alternatively recommended that CMS freeze the payment rate for myocardial PET scans at the CY 2008 payment rate of approximately $1,400 for CY 2009 to ensure greater stability in payment. Some commenters asserted that the payment rates for myocardial PET studies have shown significant volatility over the past 4 years, and requested that CMS refrain from implementing the proposed payment reduction and work towards stabilizing the payment rate. One commenter suggested placing all three myocardial PET scan CPT codes, that is 78459, 78491, and 78492, in New Technology APC 1516 (New Technology—Level XVI ($1400—$1500)), with a proposed CY 2009 payment rate of $1,450, for at least 2 years, to stabilize the payment for these services. Another commenter urged CMS to carefully review the claims data in setting the final payment rate for APC 0307.

Response: Analysis of the CY 2007 hospital outpatient claims data revealed that the HCPCS code-specific median costs for all three myocardial PET scan procedures that we proposed to retain in APC 0307 are about the same. Specifically, the HCPCS code-specific median costs of the three myocardial PET scan procedures are as follows: (1) For CPT code 78459, the median cost is approximately $924 based on 118 single claims; (2) For CPT code 78491, the median cost is approximately $1,410 based on 28 single claims; and (3) For CPT code 78492, the median cost is approximately $1,142 based on 1,809 single claims. In setting the CY 2009 payment rates for the myocardial PET scan services, according to our standard ratesetting methodology for clinical APCs to which nuclear medicine procedures are assigned, we used only those claims with a radiolabeled product reported, to ensure correctly coded claims. We packaged the cost of the diagnostic radiopharmaceuticals used in the studies into payment for the scans, as discussed in detail in section V.B.2.c. of this final rule with comment period. We believe that all of the myocardial PET scan procedures are appropriately assigned to APC 0307 based on consideration of their clinical characteristics and resource costs.

While we utilized external data in the early years of the OPPS for ratesetting for a few services, we now rely on the cost data from claims as the system has matured and we have gained additional experience in ratesetting for HOPD services. The foundation of a system of relative weights like the OPPS is the relativity of the costs of all services to one another, as derived from a standardized system that uses standardized inputs and a consistent methodology. Adoption of a ratesetting methodology for APC 0307 that is different from ratesetting for other APCs containing nuclear medicine procedures would undermine this relativity. We believe that we have sufficient claims data for the myocardial PET scan services upon which to base the CY 2009 final payment rates. In fact, the total number of claims for these services has increased steadily over the past several years. There were 2,576 claims for CY 2004; 2,874 claims for CY 2005; 3,094 claims for CY 2006; and 3,537 claims for CY 2007, the most recent year of claims available for CY 2009 ratesetting. The historical variability in OPPS payment for myocardial PET scan services does not appear to have affected the access of Medicare beneficiaries to these services. Given that these services have been assigned to APC 0307 since CY 2007, with payment based on the most current hospital claims and Medicare cost report data, we believe we are providing a stable and consistent payment methodology that appropriately reflects the hospital resources required for myocardial PET scans. Therefore, we see no reason to ''freeze'' the payment for myocardial PET scans at the CY 2008 rate when we have updated hospital claims information available for ratesetting.

Further, we do not agree with the recommendation to assign myocardial PET scan services to New Technology APC 1516, because these services are established OPPS services of moderate volume, with historical claims data available for a number of past years, and they do not fit the general criteria for services considered to be new

technology services under the OPPS. We continue to believe that assignment of CPT codes 78459, 78491, and 78492 to APC 0307 ensures appropriate payment for the services. Assignment to New Technology APC 1516, which has a CY 2009 payment rate of $1,450, would result in overpayment for myocardial PET scan services according to our most recent hospital cost data.

Comment: One commenter expressed concern with the proposed assignment of the multiple myocardial PET scan procedure, specifically CPT code 78492, to the same APC as the single myocardial PET scan procedure, specifically CPT code 78491, and believed this approach would significantly underpay providers for multiple scanning procedures. The commenter stated that multiple scans require greater hospital resources, as well as increased scan times, than single scans, and argued that the proposal would result in underpayment to the facilities providing multiple scan services. The commenter further asserted that the proposed significant reduction in payment from CY 2008 to CY 2009 would impact patient access to these services. The commenter urged CMS to reevaluate the claims data for APC 0307 to distinguish between the resources necessary to provide single versus multiple imaging studies before finalizing the proposed CY 2009 payment rate for myocardial PET scan services.

Response: Based on our CY 2007 claims data used for this final rule with comment period, the HCPCS code-specific median costs for all three myocardial PET scan services that we proposed to assign to APC 0307 are similar. Approximately 93 percent of the CY 2007 claims for myocardial PET scans are for CPT code 78492 for multiple scans, while only approximately 1 percent are for CPT code 78491, the single scan CPT code referenced by the commenter. The median cost for CPT code 78492 of approximately $1,142 is actually less than the median cost of CPT code 78491 of approximately $1,410, a counterintuitive finding that is likely the result of very few claims for CPT code 78491 from a small number of hospitals. Nevertheless, the assignment of single myocardial PET scan procedures to the same APC as multiple scan procedures has very little effect on the payment rate for APC 0307, which is largely driven by the majority of claims for multiple scan procedures. As we explained previously in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68040 through 68041) and the CY 2008 OPPS/ASC final rule with comment period (72 FR 66718), based on the CY 2007 claims data used for this final rule with comment period, we believe that the assignment of CPT codes 78459, 78491, and 78492 to a single clinical APC for CY 2009 is appropriate because the CY 2007 claims data used for CY 2009 ratesetting do not support a payment differential between single and multiple myocardial PET scan services.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to continue to assign CPT codes 78459, 78491, and 78492 for myocardial PET scan services to APC 0307, with a final APC median cost of approximately $1,131 for CY 2009.

After consideration of the public comments received, we are finalizing our CY 2009 proposals, without modification, for the configurations of APCs containing nuclear medicine procedures. The final APC assignments of all CPT codes for nuclear medicine procedures are displayed in Addendum B to this final rule with comment period.

Comment: With regard to the procedure-to-radiolabeled product claims processing edits, some commenters suggested that CMS create a modifier or a HCPCS code for hospitals to use when the hospital performs the nuclear medicine scan but does not supply the radiolabeled product. The commenters noted that this would be an appropriate situation for a reduction to payment for the nuclear medicine procedure in order to offset the packaged diagnostic radiopharmaceutical costs not incurred by the hospital when the hospital does not provide the radiopharmaceutical.

Response: It continues to be our expectation that, in accordance with the hospital bundling requirements, hospitals will provide both the diagnostic radiopharmaceutical and the nuclear medicine procedure because administration of the diagnostic radiopharmaceutical is an essential part of the nuclear medicine study. As we stated in the April 7, 2000 OPPS final rule (65 FR 18440), ''All diagnostic tests that are furnished by a hospital, directly or under arrangements, to a registered hospital outpatient during an encounter at a hospital are subject to the bundling requirements.'' We further explained that the hospital is not responsible for billing the diagnostic test if a hospital patient leaves the hospital and goes elsewhere to obtain the diagnostic test. However, when reporting a nuclear medicine procedure provided in the HOPD, the administration of the radiopharmaceutical is not separately reported because the administration is considered to be integral to the performance of the nuclear medicine procedure. Therefore, we would expect that the radiopharmaceutical and the accompanying nuclear medicine procedure that make up the complete service ''furnished to hospital patients, must be provided directly or under arrangements by the hospital and only the hospital may bill the program,'' as we also stated in the August 2, 2000 OPPS final rule (65 FR 18440).

We have provided a specific accommodation for one rare circumstance where the HOPD does not furnish a diagnostic radiopharmaceutical (or other radiolabeled product) prior to performing a nuclear medicine procedure. In the particular case where a Medicare beneficiary receives a radiolabeled product as a hospital inpatient and then requires a nuclear medicine procedure as a hospital outpatient but does not require administration of a diagnostic radiopharmaceutical, as of October 2008, we have instructed hospitals to report HCPCS code C9898 (Radiolabeled product provided during a hospital inpatient stay) with a token charge of less than $1.01 so that the claims for the nuclear medicine procedure may process to payment. In this situation, which we have been told is rare, the patient would not receive a radiolabeled product in the HOPD. We believe the hospital should receive payment for the nuclear medicine procedure provided in the HOPD and the hospital bundling rules would not present a problem because the radiolabeled product furnished to an inpatient was not provided for purposes of the nuclear medicine study. HCPCS code C9898 is recognized as a radiolabeled product code for purposes of the procedure-to-radiolabeled product edits incorporated in the I/OCE. However, we do not believe that the development of a modifier, additional HCPCS codes, or an offset methodology for other circumstances, such as the patient receiving a radiopharmaceutical in the physician's office when the nuclear medicine procedure is provided in the HOPD, would be appropriate because of the hospital bundling requirements. Moreover, in those situations where an exception is made, such as when a beneficiary is administered a therapeutic radiopharmaceutical as part of a hospital inpatient stay and then returns to the HOPD for a nuclear medicine scan without needing a diagnostic radiopharmaceutical to be administered for the study, we do use

these claims for ratesetting purposes. We believe that just as these situations are representative of the use of a nuclear medicine scan, it is also appropriate to include them for ratesetting purposes.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to provide payment for nuclear medicine procedures on OPPS claims that pass the procedure-to-radiolabeled product edits incorporated in the I/OCE, without additional provisions for bypassing those edits or offsetting the packaged diagnostic radiopharmaceutical costs included in the procedure payment if the radiopharmaceutical is administered outside the HOPD.

In summary, because we are continuing to package payment for diagnostic radiopharmaceuticals in CY 2009 as discussed further in section V.B.2.c. of this final rule with comment period, we are finalizing our CY 2009 proposal, without modification, to set the nuclear medicine procedure payment rates based on those correctly coded claims that pass the claims processing edits that ensure that a radiolabeled product is included on the nuclear medicine procedure claim. We also are finalizing the proposed APC configurations for those APCs to which nuclear medicine procedures are assigned. In doing so, we are accepting the APC Panel's March 2008 recommendation to continue to package payment for diagnostic radiopharmaceuticals for CY 2009. In addition, we are accepting another APC Panel recommendation from March 2008 to present data at the first CY 2009 APC Panel meeting on usage and frequency, geographic distribution, and size and type of hospitals performing nuclear medicine studies using radioisotopes in order to ensure that access to diagnostic radiopharmaceuticals is preserved for Medicare beneficiaries.

TABLE 5—APCS WHERE NUCLEAR MEDICINE PROCEDURES ARE ASSIGNED WITH MEDIAN COSTS CALCULATED FROM CLAIMS WITH AN ASSOCIATED RADIOLABELED PRODUCT

Final CY 2009 APC	CY 2009 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.
0395	GI Tract Imaging.
0396	Bone Imaging.
0397	Vascular Imaging.
0398	Level I Cardiac Imaging.
0400	Hematopoietic Imaging.
0401	Level I Pulmonary Imaging.
0402	Level II Nervous System Imaging.
0403	Level I Nervous System Imaging.
0404	Renal and Genitourinary Studies.
0406	Level I Tumor/Infection Imaging.
0408	Level III Tumor/Infection Imaging.
0414	Level II Tumor/Infection Imaging.

(6) Hyperbaric Oxygen Therapy

Since the implementation of the 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 OPPS 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 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 4 years. In the CY 2009 OPPS/ASC proposed rule (73 FR 41442), we proposed to continue using the same methodology to estimate a ''per unit'' median cost for HCPCS code C1300 for CY 2009 of approximately $103, using 71,866 claims with multiple units or multiple occurrences.

Comment: One commenter suggested that the payment rate per unit for HBOT was too low relative to the commenter's incurred costs for the hyperbaric oxygen and equipment. The commenter further encouraged CMS to instruct providers to be sure their charges are appropriate and offer providers specific billing guidance and instruction by providing examples of charging by the ''unit'' for multiple 30 minute sessions. The commenter noted that per unit billing can be confusing.

Response: In response to the comment on the adequacy of the proposed payment rate, the proposed methodology represents our best

approach to estimating a valid median cost upon which to base a payment rate for HBOT services for CY 2009, in the context of the per 30 minute time period specified in the HCPCS code descriptor for HCPCS code C1300. All OPPS payment rates are based on the middle or median estimated cost of providing a service or group of services. For any given service or group of services, we expect that some hospitals will incur costs higher than the payment rate and some less.

We agree with the commenter on the importance of having accurate claims data as part of our median cost calculation and that unit billing can be challenging. For all services, we do expect hospitals participating in the OPPS to be familiar with CPT and HCPCS code descriptors and to bill accordingly. We provide general direction on billing units for HCPCS codes under the OPPS in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 4, Section 20.4. We note that HCPCS code C1300 has been in use for some time. Our analysis of claims for HCPCS code C1300 for the CY 2005 OPPS proposed rule indicated that many hospitals understand unit billing for HCPCS code C1300. We observed that most hospitals billed 3 or 4 units for an HBOT session, and these multiple unit claims are the claims we used for rateseting for CY 2009.

After consideration of the public comment received, we are finalizing our CY 2009 proposal, without modification, to continue to use our established ratesetting methodology for calculating the median cost of APC 0659 for payment of HBOT, with a final CY 2009 APC median cost of approximately $101.

(7) Payment for Ancillary Outpatient Services When Patient Expires (–CA Modifier)

In the November 1, 2002 final rule with comment period (67 FR 66798), we discussed the creation of the new HCPCS–CA modifier 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. 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 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).

In the CY 2009 OPPS/ASC proposed rule (73 FR 41442), we proposed to continue to use for CY 2009 our established ratesetting methodology for calculating the median cost of APC 0375 (Ancillary Outpatient Services When Patient Expires), and we proposed to continue to make one payment under APC 0375 for the services that meet the specific conditions for using modifier –CA. We proposed to calculate the relative payment weight for APC 0375 by using all claims reporting a status indicator ''C'' procedure appended with the –CA modifier, using estimated costs from claims data for line-items with a HCPCS code assigned status indicator ''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 continue to believe that this methodology results in the most appropriate aggregate median cost for the ancillary services provided in these unusual clinical situations.

As discussed in the CY 2009 OPPS/ASC proposed rule (73 FR 41442), we believe that hospitals are reporting the –CA modifier according to the policy initially established in CY 2003. We noted that the claims frequency for APC 0375 has been relatively stable over the past few years. Although the proposed median cost for APC 0375 was slightly lower for CY 2009 than the final median cost for CY 2008, generally it has increased significantly in recent years. 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 –CA modifier 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 –CA modifier. Table 5 of the CY 2009 OPPS/ASC proposed rule showed the number of claims and the median cost for APC 0375 from CY 2006 to CY 2008. For CY 2009, the final median cost for APC 0375 of approximately $5,545 is slightly higher than the CY 2008 and proposed CY 2009 median costs.

We did not receive any public comments regarding this proposal. Therefore, we are finalizing our CY 2009 proposal, without modification, to continue to use our established ratesetting methodology for calculating the median cost of APC 0375, which has a final CY 2009 APC median cost of approximately $5,545.

Table 6 below shows the number of claims and the final median cost for APC 0375 from CY 2006 to CY 2009.

TABLE 6—CLAIMS FOR ANCILLARY OUTPATIENT SERVICES WHEN PATIENT EXPIRES (–CA MODIFIER) FOR CYS 2006 THROUGH 2009

Prospective payment year	Number of claims	Final approximate APC median cost
CY 2006	370	$2,717
CY 2007	260	3,549
CY 2008	183	4,945
CY 2009	168	5,545

e. 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. Bundling 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 typically are low in volume and/or incorrectly coded. We refer readers to section II.A.4. of 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).

We continue to consider the development and implementation of larger payment bundles, such as composite APCs, a long-term policy objective for the OPPS and continue to explore other areas where this payment model may be utilized. In developing the CY 2009 OPPS/ASC proposed rule, we followed the same methodology for identifying possible composite APCs as we did for CY 2008. Specifically, we examined the multiple procedure claims that we could not convert to single procedure claims to identify common combinations of services for which we have relatively few single procedure claims. We then performed a clinical assessment of the combinations that we identified to determine whether our findings were consistent with our understanding of the services furnished. In addition, consistent with our stated intention to involve the APC Panel in our future exploration of how we can develop encounter-based and episode-based payment groups (72 FR 66614), we also specifically explored a possible composite APC for radioimmunotherapy in response to a recommendation of the APC Panel from its September 2007 meeting.

After performing claims analysis and clinical assessments as described earlier, and taking into consideration the recommendation of the APC Panel from its March 2008 meeting that we continue pursuing a radioimmunotherapy composite APC, we did not propose a composite APC payment for radioimmunotherapy for CY 2009, as discussed further in section V.B.4. of this final rule with comment period. However, in the CY 2009 OPPS/ASC proposed rule (73 FR 41450), we proposed to expand the composite APC model to one new clinical area for CY 2009, multiple imaging services, as described in detail in section II.A.2.e.(5) of this final rule with comment period. We also proposed to continue for CY 2009 our established composite APC policies for extended assessment and management, low dose rate (LDR) prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, and mental health services, as discussed in sections II.A.2.e.(1), II.A.2.e.(2), II.A.2.e.(3), and II.A.2.e.(4), respectively, of this final rule with comment period (73 FR 41443).

Comment: Many commenters supported the development and implementation of composite APCs as a mechanism to encourage efficient and effective care and to use multiple procedure claims that otherwise would not be available for ratesetting because they include multiple separately payable procedures furnished on the same date of service. The commenters remarked that the number of single bills available for ratesetting for certain procedures (particularly those requiring coding combinations to represent a complete service) remain a very small percentage of total billed claims, and recommended that CMS develop composite APCs in several clinical areas in order to improve OPPS payment accuracy and include more correctly coded, multiple procedure claims in ratesetting. For example, several commenters urged CMS to create composite APCs for procedures involving cardiac resynchronization therapy defibrillator (CRT–D) or cardiac resynchronization therapy pacemaker (CRT–P) devices. The commenters argued that the procedures involved in the implantation of CRT–D and CRT–P devices are major, separately payable services that, if correctly coded, are always represented by the submission of at least two CPT codes. A number of commenters recommended the development of ''composite'' APCs to address their concerns regarding the proposed packaging of certain items and services, specifically suggesting the creation of ''composite'' APC payments for various combinations of individual services and specific packaged items or services, such as bronchoscopy procedures with endobronchial ultrasound or nuclear medicine procedures combined with specific diagnostic radiopharmaceuticals.

In contrast to the commenters requesting that CMS create additional composite APCs, several commenters remarked generally that CMS should proceed cautiously as it expands service bundling, and should not implement additional composite methodologies until adequate data are available to evaluate the effectiveness and impact on beneficiary access to care of the composite policies implemented in CY 2008. Some commenters urged CMS to reevaluate the concept of composite APCs to ensure they are truly meeting the objective of encouraging more cost efficient care, are not unfairly penalizing hospitals because of the acuity of the patients they treat, and are not making the system unnecessarily complex.

Response: We agree with commenters that the composite APC model is an important and effective mechanism for promoting efficiency and paying more appropriately for packages of services. The composite payment methodology also enables us to use more claims data and generates payment rates that more accurately reflect the reality of how hospitals furnish services. Therefore, we will carefully explore the commenters' suggestions for additional composite APCs when we assess what payment policy changes might be appropriate in the future. We also will consider bringing these and other composite ideas to the APC Panel for further discussion.

We believe we are proceeding at an appropriate pace in the development of composite APCs. We did not receive any comments on the CY 2009 OPPS/ASC proposed rule indicating there were access problems resulting from the implementation of composite APCs in CY 2008. Furthermore, we believe that the composite payment methodology improves the accuracy of OPPS payment, and we would not expect access problems or other difficulties to arise from a methodology that utilizes more complete and valid claims in ratesetting than our standard APC ratesetting methodology. We also do not agree that the composite methodology makes the OPPS payment system unnecessarily complex, because it utilizes data from multiple procedure claims as reported by hospitals and does not require hospitals to change their coding and billing practices in any way.

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66650), our initial work on developing composite APCs arose, in part, from our attempts to develop an approach to utilize common multiple procedure claims that were not otherwise available for ratesetting because they included multiple separately payable procedures furnished on the same date of service. Composite APCs were designed to expand the payment bundles of the OPPS by providing a single payment for the totality of care provided in a hospital outpatient encounter that would be reported with two or more HCPCS codes for otherwise separately payable component services. Similarly, in CY 2008 the expanded unconditional packaging of items and services also allowed us to use more claims data from what would otherwise be multiple procedure claims and to expand the OPPS payment bundles. We do not consider some of the recommendations by commenters to provide unique payments for specific combinations of separately payable services with certain packaged items and services to be

''composite'' APCs that move toward a single payment for that totality of a service because, in such cases, we are already providing only a single payment for the totality of the service, including the packaged items and services. Such an approach would lead to smaller OPPS payment bundles, would not utilize additional multiple procedure claims, and would reduce the incentives for hospital efficiency created by packaging payment.

After consideration of the public comments received, for CY 2009 we are finalizing our proposal, without modification, to continue our established composite APC policies for extended assessment and management, LDR prostate brachytherapy, cardiac electrophysiologic evaluation and ablation, and mental health services, as discussed in sections II.A.2.e.(1), II.A.2.e.(2), II.A.2.e.(3), and II.A.2.e.(4), respectively, of this final rule with comment period. We also are implementing a new composite payment methodology for multiple imaging services provided on the same date of service, as discussed further in section II.A.2.e.(5) of this final rule with comment period.

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

In the CY 2009 OPPS/ASC proposed rule (73 FR 41443), we proposed to continue to include composite APC 8002 (Level I Extended Assessment and Management Composite) and composite APC 8003 (Level II Extended Assessment and Management Composite) in the OPPS for CY 2009. In addition, we proposed to include HCPCS code G0384 (Level 5 hospital emergency department visit provided in a type B emergency department) in the criteria that determine eligibility for payment for composite APC 8003 (73 FR 41443) for CY 2009. For CY 2008, we created these two new 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 admission 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 admission to observation 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) 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 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 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 2009 median costs for these composite APCs. The general composite APC logic and observation care reporting criteria have also been included in updates to the Claims Processing and Benefit Policy Manuals through Change Request 5916 (Transmittals 82 and 1145), dated February 8, 2008, and we did not propose to change these criteria for the CY 2009 OPPS (73 FR 41443).

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 section XI. of the CY 2008 final rule with comment period (72 FR 66812). In the CY 2009 OPPS/ASC proposed rule (73 FR 41443), we did not propose to change these reporting requirements for the CY 2009 OPPS. 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.

As noted in detail in sections IX.C. and XI. of the CY 2008 OPPS/ASC final rule with comment period (72 FR 66802 through 66805 and 66814), we saw a normal and stable distribution of clinic and emergency department visit levels. We do not expect to see an increase in the proportion of visit claims for high level visits as a result of the new composite APCs adopted for CY 2008 and proposed for CY 2009. Similarly, we expect that hospitals will not purposely change their visit guidelines or otherwise upcode clinic and emergency department visits reported with observation care solely for the purpose of composite payment. As stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66648), we expect to carefully monitor any changes in billing practices on a service-specific and hospital-specific level to determine whether there is reason to request that Quality Improvement Organizations (QIOs) review the quality of care furnished, or to request that Benefit Integrity contractors or other contractors review the claims against the medical record. However, we will not have claims available for analysis that reflect the new CY 2008 payment policy for the extended assessment and management composite APCs until the CY 2010 annual OPPS rulemaking cycle.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41444), we proposed to continue the extended assessment and management composite APC payment methodology for APCs 8002 and 8003 for CY 2009. As stated earlier, we also proposed to continue the general reporting requirements for observation services reported with HCPCS code G0378. We continue to believe that the composite APCs 8002 and 8003 and the related policies provide the most appropriate means of paying for these services. We proposed to calculate the median costs for APCs 8002 and 8003 using all single and ''pseudo'' single procedure claims for CY 2007 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 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 admission 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 provided on the same date of service or one day before the date of service for HCPCS code G0378. (As discussed in detail below, we proposed to add HCPCS code G0384 to the eligibility criteria for composite APC 8003 for CY 2009.)

We applied the standard packaging and trimming rules to the claims before calculating the proposed CY 2009 median costs. The proposed CY 2009 median cost resulting from this process for composite APC 8002 was approximately $364, which was calculated from 14,968 single and ''pseudo'' single bills that met the required criteria. The proposed CY 2009 median cost for composite APC 8003 was approximately $670, which was calculated from 83,491 single and ''pseudo'' single bills that met the required criteria. This is the same methodology we used to calculate the medians for composite APCs 8002 and 8003 for the CY 2008 OPPS (72 FR 66649).

As discussed in more detail in section IX.B. of this final rule with comment period, in the CY 2009 OPPS/ASC proposed rule (73 FR 41444), we proposed to reassign HCPCS code G0384 from APC 0608 (Level 5 Hospital Clinic Visits) to APC 0616 (Level 5 Emergency Visits) for CY 2009. Consistent with this change for CY 2009, in the CY 2009 OPPS/ASC proposed rule (73 FR 41444), we also proposed to add HCPCS code G0384 to the eligibility criteria for payment of composite APC 8003. Because these visits are rare, we would not expect that adding HCPCS code G0384 to the eligibility criteria for payment for extended assessment and management composite APC 8003 would significantly increase the relative frequency of the Type B emergency department Level 5 visits reported using HCPCS code G0384.

As discussed further in sections III.D and IX. of this final rule with comment period and consistent with our CY 2008 final policy, 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 0629), we would 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 would result in the most accurate cost estimates for APCs 0604 through 0617 and 0626 through 0629 for CY 2009.

Also as discussed in section XIII.A.1. of this final rule with comment period, for CY 2009, in the CY 2009 OPPS/ASC proposed rule (73 FR 41520 through 41521), we proposed to replace current status indicator ''Q'' with three new separate status indicators: ''Q1,'' ''Q2,'' and ''Q3'' for CY 2009. In the CY 2009 OPPS, ASC proposed rule (73 FR 41520 through 41521), we indicated our belief that this proposed change would make our policy more transparent to hospitals and would facilitate the use of status indicator-driven logic in our ratesetting calculations, and in hospital billing and accounting systems. Under this proposal, status indicator ''Q3'' would be assigned to all codes that may be paid through a composite APC based on composite-specific criteria or separately through single code APCs when the criteria are not met. Therefore, we proposed that each of the direct admission, clinic, and emergency department visit codes that may be paid through composite APCs 8002 and 8003 be assigned status indicator ''Q3'' for CY 2009. We proposed that HCPCS code G0378 would continue to be always packaged by assigning the HCPCS code status indicator ''N,'' its current status indicator under the CY 2008 OPPS.

At its March 2008 meeting, the APC Panel recommended that CMS provide additional data related to the frequency and median cost for the extended assessment and management composite APCs and length-of-stay frequency distribution data for observation services, with additional detail at the 24–48 hour and greater than 48 hour levels. At the APC Panel's August 2008 meeting, we provided the additional data as requested. After reviewing the data presented, the APC Panel requested that additional data on observation services with longer lengths of stay, analyzed by hospital characteristics, be presented at the next meeting of the APC Panel, that is, the APC Panel's first CY 2009 meeting. In addition, the APC Panel requested that an analysis of CY 2008 claims data for clinic visits, emergency department visits (Type A and Type B), and extended assessment and management composite APCs be presented at the first CY 2009 meeting of the APC Panel.

At its August 2008 meeting, the APC Panel also recommended that CMS adopt the CY 2009 proposals related to the extended assessment and management composite APCs, especially in reference to the inclusion of the Level 5 Type B emergency department visit HCPCS code in APC 8003 (Level II Extended Assessment and Management Composite). Finally, the APC Panel recommended continuation of the Visits and Observation Subcommittee's work. We are accepting each of the APC Panel's recommendations and will provide additional data and analyses as requested at the first CY 2009 meeting of the APC Panel.

Comment: Several commenters expressed continued support for payment of composite APC 8003, which includes a high level emergency department visit or critical care billed with observation services. In addition, several commenters supported CMS' proposal to include the Level 5 Type B ED visits, reported with HCPCS code G0384, to the eligibility criteria for payment of composite APC 8003 (Level II Extended Assessment and Management Composite). Another commenter asserted that the extended assessment and management APC criteria are arbitrary because they do not include lower level emergency department and clinic visits. The latter commenter believed that observation care is medically necessary in association with low level visits in some cases and that the observation care is often identical to the observation provided to individuals in association with high level visits. Therefore, the commenter concluded that the proposed composite payment criteria were arbitrary because no payment is made for the medically necessary observation care provided in association with a low level visit.

Response: We appreciate the commenter's support for continued payment of the extended assessment and management composite APCs and for the addition of HCPCS code G0384 to the eligibility criteria for payment of composite APC 8003.

In response to the commenter who stated that the composite APC payment criteria are arbitrary, payment for all

observation care is packaged under the OPPS but, as we explained in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66648), we believe that observation care only rises to the level of a major component service that could be paid through a composite APC when it is provided for 8 hours or more in association with a high level clinic or emergency department visit. Therefore, we do not believe it would be appropriate to provide payment for observation care in association with a low level clinic or emergency department visit through a composite APC because we do not believe that two major component services are provided in such cases.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66649), we estimated that roughly 90 percent of the instances of separately payable observation care reported in CY 2006 would be eligible for payment through composite APCs 8002 and 8003, using the CY 2008 final criteria. We continue to believe that most instances of observation that were separately payable in CY 2006 would have been eligible for payment under composite APCs 8002 and 8003 under the CY 2009 OPPS. In addition, some of the packaged observation care that was provided in CY 2006 would now be eligible for payment through composite APCs 8002 and 8003 because we eliminated the diagnosis requirement for CY 2008. However, for observation care provided under circumstances that do meet the criteria for composite APC payment, including observation in association with low level clinic or emergency department visits, we continue to believe that the observation is ancillary and supportive to those other services provided to the patient on the same day. Therefore, in such cases, hospitals would receive payment for the observation care as it is packaged into payment for the other separately payable services, such as the low level clinic or emergency department visit.

After consideration of the public comments received and the recommendations of the APC Panel, we are finalizing our CY 2009 proposals, without modification, for payment of composite APCs 8002 and 8003. The CY 2008 criteria and payment methodology finalized for composites APCs 8002 and 8003 will continue, consistent with the APC Panel's August 2008 recommendation in support of our CY 2009 proposals for payment of extended assessment and management composite APCs. As discussed in section IX.B. of this final rule with comment period, we are also finalizing our proposal to reassign HCPCS code G0384 from APC 0608 (Level 5 Hospital Clinic Visits) to APC 0616 (Level 5 Emergency Visits). Moreover, we are finalizing our CY 2009 proposal, without modification, to include HCPCS code G0384 in the criteria that determine eligibility for payment of composite APC 8003, consistent with the APC Panel's August 2008 recommendation that we should adopt this proposal. The final CY 2009 median cost for composite APC 8002 is approximately $367, which was calculated from 17,501 single and ''pseudo'' single bills that met the required criteria. The final CY 2009 median cost for composite APC 8003 is approximately $660, which was calculated from 150,088 single and ''pseudo'' single bills that met the required criteria.

Finally, as discussed in section XIII.A.1, of this final rule with comment period, we are finalizing our CY 2009 proposal to replace current status indicator ''Q'' with three new separate status indicators: ''Q1,'' ''Q2,'' and ''Q3.'' Therefore, each of the direct admission, clinic, and emergency department visit codes that may be paid through composite APCs 8002 and 8003 are assigned status indicator ''Q3'' (Codes that May be Paid Through a Composite APC) for CY 2009 in Addendum B to this final rule with comment period.

As we indicated in the CY 2008 OPPS ASC final rule with comment period, (72 FR 66802 through 66805 and 66814), we saw a normal and stable distribution of clinic and emergency department visits. We continue not to expect to see an increase in the proportion of visit claims for high level visits as a result of the new composite APCs adopted for CY 2008 and proposed for CY 2009. Similarly, we expect that hospitals will not purposely change their visit guidelines or otherwise upcode clinic and emergency department visits reported with observation care solely for the purpose of composite payment. We would also remind readers that reasonable and necessary observation care is a supportive and ancillary service for which payment is always packaged. When the criteria for payment of either composite APC 8002 or 8003 are met, then the costs associated with observation care reported with HCPCS code G0378 are attributed to the total costs of that composite APC. When the criteria are not met, the costs of observation care are packaged with the costs of the separately payable independent services on the claim, usually the clinic or emergency department visit. Those costs are reflected in the APC payments for the independent services. Therefore, payment is made for observation care as part of the payment for the independent service. The absence of separate payment for observation care does not equate to the absence of Medicare coverage for the service.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41444), we also proposed that the payment policy for separate payment of HCPCS code G0379 that was finalized for the CY 2008 OPPS (72 FR 66814 through 66815) would continue to apply for CY 2009 when the criteria for payment of this service through composite APC 8002 are not met. The criteria for payment of HCPCS code G0379 under either composite APC 8002, as part of the extended assessment and management composite service, or APC 0604, as a separately payable individual service are: (1) Both HCPCS codes G0378 and G0379 are reported with the same date of service; and (2) no service with a status indicator of ''T'' or ''V'' or Critical Care (APC 0617) is provided on the same date of service as HCPCS code G0379. If either of the above criteria is not met, HCPCS code G0379 is assigned status indicator ''N'' and its payment is packaged into the payment for other separately payable services provided in the same encounter.

We did not receive any public comments concerning this proposal. Therefore, we are finalizing our CY 2009 proposal, without modification, for separate or composite APC payment of HCPCS code G0379 under the same circumstances as the final CY 2008 policy. If the criteria for separate or composite APC payment are not met, payment for HCPCS code G0379 is packaged into payment for the other separately payable services provided.

(2) LDR Prostate Brachytherapy Composite APC (APC 8001)

LDR prostate brachytherapy is a treatment for prostate cancer in which needles or catheters are inserted into the prostate, followed by permanent implantation of radioactive sources into the prostate through hollow needles or 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 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, have 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 only 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 contribute to 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, billed 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.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41445), we proposed to continue paying for LDR prostate brachytherapy services in CY 2009 using the composite APC methodology proposed and implemented for CY 2008. That is, we proposed to use CY 2007 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 practice, we would not 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) to which CPT codes 55875 and 77778 are assigned respectively; median costs for APCs 0163 and 0651 would continue to be calculated using single procedure claims. We note that we inadvertently cited APC 0313 instead of APC 0651 as the assigned APC for CPT code 77778 in the CY 2009 OPPS/ASC proposed rule at 73 FR 41445. However, the correct APC (0651) assignment for CPT code 77778 was included in Addenda B and M to the proposed rule, and our CY 2009 proposal was to continue to assign CPT code 77778 to APC 0651. As discussed in section XIII.A.1. of this final rule with comment period, we also proposed to use new status indicator ''Q3'' (Codes that May be Paid Through a Composite APC), to denote HCPCS codes such as CPT codes 55875 and 77778 that may be paid through a composite APC for publication and payment purposes for CY 2009, rather than status indicator ''Q'' that is being used in CY 2008. In the CY 2009 OPPS/ASC proposed rule (73 FR 41520 through 41521), we proposed the status indicator change to facilitate identification of HCPCS codes that may be paid through composite APCs and to facilitate development of the composite APC median costs for CY 2009.

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 2007 claims data available for the CY 2009 proposed rule, we were able to use 6,897 claims that contained both CPT code 77778 and 55875 to calculate the median cost upon which the CY 2009 proposed payment for composite APC 8001 was based. The proposed median cost for composite APC 8001 for CY 2009 was approximately $3,509. This was an increase compared to the CY 2008 OPPS/ASC final rule with comment period in which we calculated a final median cost for this composite APC of approximately $3,391 based on a full year of CY 2006 claims data. The CY 2009 proposed composite APC median was slightly less than $3,581, the sum of the proposed median costs for APCs 0163 and 0651 ($2,388 + $1,193), the APCs to which CPT codes 55875 and 77778 map if one service is billed on a claim without the other. We stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41445) that we believe the proposed CY 2009 median cost for composite APC 8001 of approximately $3,509, calculated from claims we believe to be correctly coded, would result in a reasonable and appropriate payment rate for this service in CY 2009.

Comment: One commenter supported the continuation of the LDR prostate brachytherapy composite APC but urged CMS to closely monitor utilization to ensure access to this therapy is not compromised by this change in payment policy.

Response: We appreciate the commenter's thoughts on the LDR prostate brachytherapy composite APC. As stated previously, we believe that the composite payment methodology improves the accuracy of OPPS payment, and we would not expect access problems or other difficulties to arise from a methodology that utilizes more complete and valid claims in ratesetting than our standard APC ratesetting methodology for the services described by CPT codes 55875 and 77778 when performed together on the same date of service. When the CY 2008 claims become available for the CY 2010 OPPS rulemaking cycle, we will examine utilization of LDR prostate brachytherapy services to ensure no inappropriate changes in utilization have occurred.

After consideration of the public comment received, we are finalizing our CY 2009 proposal, without modification, to continue paying for LDR prostate brachytherapy services using the composite APC methodology implemented for CY 2008. We were able to use 845 claims that contained both CPT codes 77778 and 55875 to calculate the median cost upon which the CY 2009 final payment for composite APC 8001 is based. The final median cost for composite APC 8001 for CY 2009 is approximately $2,967. We note that this is a decrease in median cost compared to the CY 2009 OPPS/ASC proposed rule in which we calculated a proposed median cost for this composite APC of approximately $3,509. We also note that there is a significant decrease in the number of claims used for calculating the median cost for APC from the CY 2009 proposed rule to this final rule with comment period.

We believe that the decreases in both the median cost for APC 8001 and the number of claims used to calculate the median cost are attributable to the removal of CPT codes in the radiation oncology series of CPT codes from the

bypass list in response to public comments because the codes did not meet the empirical criteria for inclusion on the bypass list, as discussed in section II.A.1.b.of this final rule with comment period. We believe that some of the CPT codes that were removed from the bypass list, which are paid separately in addition to the LDR prostate brachytherapy composite APC, occur so frequently on claims that meet the criteria for LDR prostate brachytherapy composite payment that their removal from the bypass list resulted in the significant drop in the number of claims that could be used to calculate the median cost for APC 8001. However, our final CY 2009 median cost for APC 8001 should be a more accurate reflection of the cost of the services for which the composite payment is made than the proposed CY 2009 median cost, because it is most likely that the packaged costs that should have been associated with the radiation oncology codes on the bypass list were wrongly attributed to the cost of the LDR prostate brachytherapy composite APC in the CY 2009 proposed rule, as discussed in more detail in response to public comments in section II.A.1.b. of this final rule with comment period. The APC 8001 median cost that we calculated for this final rule with comment period no longer includes the packaging that should have been attributed to the codes that were on the bypass list but did not meet the empirical criteria for the bypass list. Moreover, the line-item costs for the radiation oncology codes that failed the empirical criteria for the bypass list are no longer being used as ''pseudo'' single claims without their associated packaging to set the payment rates for those codes. The median costs for these codes should also be more accurate because the ''pseudo'' single procedure claims that lacked the appropriate packaging are no longer being used to set the medians for them.

The final CY 2009 median cost for composite APC 8001 of approximately $2,967 is slightly less than $3,163, the sum of the median costs for APC 0163 and APC 0651 ($2,316 + $847), the APCs to which CPT codes 55875 and 77778 map if one service is billed on a claim without the other. These CPT codes are assigned status indicator ''Q3'' in Addendum B to this final rule with comment period to identify their status as potentially payable through a composite APC. Their composite APC assignment is identified in Addendum M to this final rule with comment period.

(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 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 was 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, and Table 6 in the CY 2009 OPPS/ASC proposed rule, reprinted as Table 7 below, identified the CPT codes that were assigned to groups A and B. For a full discussion of how we identified the group A and group B procedures and established the CY 2008 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.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41446), we proposed to continue paying for cardiac electrophysiologic evaluation and ablation services in CY 2009 using the composite APC methodology established for CY 2008. Consistent with our CY 2008 practice, we would not use the claims that met the composite payment criteria in the calculation of the median costs for APCs 0085 (Level II Electrophysiologic Procedures) and 0086 (Level III Electrophysiologic Procedures), to which the HCPCS codes in both groups A and B for composite APC 8000 were otherwise assigned. Median costs for APCs 0085 and 0086 would continue to be calculated using single procedure claims. As discussed in section XIII.A.1. of this final rule with comment period, we also proposed to use new status indicator ''Q3'' (Codes that May be Paid Through a Composite APC) to denote HCPCS codes such as the cardiac electrophysiologic evaluation and ablation CPT codes that may be paid through a composite APC for publication and payment purposes for CY 2009, rather than the status indicator ''Q'' that is being used in CY 2008.

We continue to believe that the composite APC 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 2007 claims data available for the CY 2009 OPPS/ASC proposed rule, we were able to use 5,603 claims containing a combination of group A and group B codes and calculated a proposed median cost of approximately $9,174 for composite APC 8000. This was an increase

compared to the CY 2008 OPPS/ASC final rule with comment period in which we calculated a final median cost for this composite APC of approximately $8,438 based on a full year of CY 2006 claims data. We stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41446) that we believe that the proposed median cost of $9,174 calculated from a high volume of correctly coded multiple procedure claims resulted 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 of the CY 2009 OPPS/ASC proposed rule, reprinted as Table 7 below, listed the groups of procedures upon which we proposed to base composite APC 8000 for CY 2009.

Comment: One commenter expressed support for CMS' proposal to continue using the composite APCs created in CY 2008, in particular the composite APC for cardiac electrophysiologic evaluation and ablation services.

Response: We appreciate the commenter's support for the composite payment methodology in general and the composite APC for cardiac electrophysiologic evaluation and ablation in particular.

After consideration of the public comment received, we are finalizing our CY 2009 proposal, without modification, to continue paying for cardiac electrophysiologic evaluation and ablation services using the composite APC methodology implemented for CY 2008. For this final rule with comment period, we were able to use 6,105 claims from CY 2007 containing a combination of group A and group B codes and calculated a final median cost of approximately $9,206 for composite APC 8000. This is an increase compared to the CY 2008 OPPS/ASC final rule with comment period in which we calculated a final median cost for this composite APC of approximately $8,438 based on a full year of CY 2006 claims data. We believe that the final median cost of $9,206 calculated from a high volume of correctly coded multiple procedure claims results in an accurate and appropriate final payment for cardiac electrophysiologic evaluation and ablation services when at least one evaluation service is furnished during the same clinical encounter as at least one ablation service. Table 7, below, lists the groups of procedures upon which we are basing composite APC 8000 for CY 2009. These CPT codes are assigned status indicator ''Q3'' in Addendum B to this final rule with comment period to identify their status as potentially payable through a composite APC. Their composite APC assignment is identified in Addendum M to this final rule with comment period.

TABLE 7—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 2009 HCPCS code	Final single code CY 2009 APC	Final CY 2009 SI (composite)
Group A			
Comprehensive electrophysiologic evaluation with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording, including insertion and repositioning of multiple electrode catheters, without induction or attempted induction of arrhythmia	93619	0085	Q3
Comprehensive electrophysiologic evaluation including insertion and repositioning of multiple electrode catheters with induction or attempted induction of arrhythmia; with right atrial pacing and recording, right ventricular pacing and recording, His bundle recording	93620	0085	Q3
Group B			
Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	93650	0085	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathways, accessory atrioventricular connections or other atrial foci, singly or in combination	93651	0086	Q3
Intracardiac catheter ablation of arrhythmogenic focus; for treatment of ventricular tachycardia	93652	0086	Q3

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

In the CY 2009 OPPS/ASC proposed rule (73 FR 41446), we proposed to continue our longstanding policy of limiting the aggregate payment for specified less 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 2009. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 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, and 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.

For CY 2009, as discussed further in section X.B. of this final rule with comment period, we proposed to create two new APCs, 0172 (Level I Partial Hospitalization (3 services)) and 0173 (Level II Partial Hospitalization (4 or more services)), to replace APC 0033 (Partial Hospitalization), which we proposed to delete for CY 2009 (73 FR 41446). In summary, when a community mental health center (CMHC) or hospital provides three units of partial hospitalization services and meets all other partial hospitalization payment criteria, the CMHC or hospital would be paid through APC 0172. When the CMHC or hospital provides four or more units of partial hospitalization services and meets all other partial hospitalization payment criteria, the hospital would be paid through APC 0173. In the CY 2009 OPPS/ASC proposed rule (73 FR 41446 through 41447), we proposed to set the CY 2009 payment rate for mental health

composite APC 0034 at the same rate as APC 0173, which is the maximum partial hospitalization per diem payment. In the proposed rule, we explained that we believed 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 0173. Through the I/OCE, when the 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 would exceed the maximum per diem partial hospitalization payment [listed as APC 0173 (Level II Partial Hospitalization (4 or more services))], those specified mental health services would be assigned to APC 0034 (Mental Health Services Composite), which has the same payment rate as APC 0173, and the hospital would be paid one unit of APC 0034. In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66651), we clarified that this longstanding policy regarding payment of APC 0034 for combinations of independent mental health services provided in a single hospital encounter resembles the payment policy for composite APCs that we finalized for LDR prostate brachytherapy and cardiac electrophysiologic evaluation and ablation services for CY 2008. Similar to the logic for those two composite APCs, the I/OCE currently determines, and we proposed for CY 2009 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 0173 per diem rate for partial hospitalization for all of the specified mental health services furnished on that date of service. However, we note that this established policy for payment of APC 0034 differs from the payment policies for the LDR prostate brachytherapy and cardiac electrophysiologic evaluation and ablation composite APCs because APC 0034 is only paid if the sum of the individual payment rates for the specified mental health services provided on one date of service exceeds the APC 0034 payment rate.

For CY 2008 (72 FR 66651), we changed the status indicator to ''Q'' for the HCPCS codes that describe the specified mental health services to which APC 0034 applies because those codes are conditionally packaged when the sum of the payment rates for the single code APCs to which they are assigned exceeds the per diem payment rate for partial hospitalization. For CY 2009, we proposed to change the status indicator from ''Q'' (Packaged Services Subject to Separate Payment under OPPS Payment Criteria) to ''Q3'' (Codes that May be Paid Through a Composite APC), for those HCPCS codes that describe the specified mental health services to which APC 0034 applies. This was consistent with our proposal to change the status indicator from ''Q'' to ''Q3'' for all HCPCS codes that may be paid through composite APCs, in order to further refine our identification of the different types of conditionally packaged HCPCS codes that were previously all assigned the same status indicator ''Q'' under the OPPS. In the CY 2009 OPPS/ASC proposed rule (73 FR 41447), we proposed to apply this status indicator policy to the HCPCS codes that were assigned to composite APC 0034 in Addendum M to the proposed rule. We also proposed to change the status indicator from ''P'' (Partial Hospitalization) to ''S'' (Significant Procedure, Not Discounted when Multiple), for APC 0034. Although APC 0034 has been historically assigned status indicator ''P'' under the OPPS, this APC provides payment for mental health services that are furnished in an HOPD outside of a partial hospitalization program. As we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41447), this proposed status indicator change should have no practical implications for hospitals from a billing or payment perspective. Rather, we believed that it would be more appropriate to assign status indicator ''S'' to an APC that describes mental health services that are provided outside of a partial hospitalization program (73 FR 41447). We refer readers to section XIII.A. of this final rule with comment period for a complete discussion of status indicators and our status indicator changes for CY 2009.

Comment: Several commenters were concerned that claims data from CMHCs and hospitals were used to calculate the proposed payment for APC 0173. The payment for APC 0173 would be the upper limit of payment a hospital could receive for outpatient mental health services provided in one day. These commenters believed that hospital cost data, and not CMHC cost data, should be used to set payment rates for hospital services. One commenter believed that the proposed payment rate for APC 0173 was too low and, therefore, established the mental health cap on payment of HOPD mental health services at an inappropriately low payment rate. The commenter noted that most patients receiving hospital outpatient mental health services generally receive four or more services per day, for 1 to 3 days. In these cases, according to the commenter, if an HOPD provided four particular mental health services in one day, that department of the hospital would receive full payment for the first two services, partial payment for the third service, and no payment for the fourth service.

Response: As discussed in detail in section X. of this final rule with comment period, the payment rates for APCs 0172 and 0173 are set consistent with hospital-only cost data for CY 2009, instead of using both hospital and CMHC cost data. This final policy results in an increase of the median cost of APC 0173 from approximately $174 as proposed to approximately $200, using hospital-only cost data. Hospital-only data have been used in the past to set the PHP payment rates when the CMHC data were unavailable or too volatile to use. This year using the CMHC data would significantly reduce the current rate and negatively impact hospital-based PHPs. Additionally, using only the hospital-based PHP data results in a Level II Partial Hospitalization rate (APC 0173) that is close to the current payment level ($203). Therefore, we are finalizing the two-tiered payment rates as proposed, but using hospital-based PHP data only.

As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66739), 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, and we do not believe that we should pay more for a day of individual mental health services under the OPPS. The mental health payment limitation will rise and fall in the same manner as payment for partial hospitalization services. We note that our final CY 2009 policy which sets the payment rate for APC 0173 for partial hospitalization services based on hospital-only cost data for CY 2009 results in payment for APC 0034, the limit on aggregate payment for specified less intensive mental health services provided on one day in the HOPD, to now be based on hospital cost data, as requested by several commenters.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to limit the aggregate

payment for specified less intensive outpatient mental health services furnished on the same date by a hospital to the payment for a day of partial hospitalization, specifically APC 0173. For CY 2009, we are also finalizing, without modification, our proposal to change the status indicator from ''Q'' to ''Q3'' for those HCPCS codes that describe the specified mental health services to which APC 0034 applies. For CY 2009, we also are finalizing the proposal to change the status indicator for APC 0034 from ''P'' to ''S.''

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

Under current OPPS policy, hospitals receive a full APC payment for each imaging service on a claim, regardless of how many procedures are performed during a single session using the same imaging modality or whether the procedures are performed on contiguous body areas. In response to a 2005 MedPAC recommendation to reduce the technical component payment for multiple imaging services performed on contiguous body areas, CMS proposed a payment reduction policy for multiple imaging procedures performed on contiguous body areas in both the CY 2006 MPFS proposed rule (70 FR 45849 through 45851) and the CY 2006 OPPS proposed rule (70 FR 42748 through 42751). In the March 2005 MedPAC report entitled, ''Report to the Congress: Medicare Payment Policy,'' MedPAC concluded that Medicare's physician's office payment rates for imaging services were based on each service being provided independently and that the rates did not account for efficiencies that may be gained when multiple studies using the same imaging modality are performed in the same session. In both the CY 2006 MPFS proposed rule (70 FR 45849) and the CY 2006 OPPS proposed rule (70 FR 42751), we suggested that although each imaging procedure entails the use of hospital resources, including certain staff, equipment, and supplies, some of those resource costs are not incurred twice when the procedures are performed in the same session and thus, should not be paid as if they were incurred twice. Specifically, for CY 2006, for both the MPFS and the OPPS, we proposed to apply a 50-percent reduction in the payment for certain second and subsequent imaging procedures performed during the same session, similar to the longstanding OPPS policy of reducing payments for certain second and subsequent surgical procedures performed during the same operative session. We developed the 50-percent reduction estimate using MPFS input data to estimate the practice expense resources associated with equipment time and indirect costs that would not occur for the second and subsequent procedures. We proposed that the reduction would apply only to individual services within 11 designated imaging families, which were comprised of procedures utilizing similar modalities across contiguous body areas and developed based on MPFS billing data. The imaging modalities included in the proposal were ultrasound, computed tomography (CT), computed tomographic angiography (CTA), magnetic resonance imaging (MRI), and magnetic resonance angiography (MRA). Prior to making the proposal for the OPPS, we confirmed that the CY 2004 OPPS claims for the CY 2006 OPPS update demonstrated comparable clustering of imaging procedures by modality and within family. The OPPS and MPFS imaging services provided across families would not be subject to the reduction policy as proposed for CY 2006. The proposed 11 families of imaging services for the proposed CY 2006 OPPS and MPFS multiple imaging payment reduction policy were as follows:

- Ultrasound (Chest/Abdomen/Pelvis-Non-Obstetrical)
- CT and CTA (Chest/Thorax/Abd/Pelvis)
- CT and CTA (Head/Brain/Orbit/Maxillofacial/Neck)
- MRI and MRA (Chest/Abd/Pelvis)
- MRI and MRA (Head/Brain/Neck)
- MRI and MRA (Spine)
- CT (Spine)
- MRI and MRA (Lower Extremities)
- CT and CTA (Lower Extremities)
- MR and MRI (Upper Extremities and Joints)
- CT and CTA (Upper Extremities)

In response to the multiple imaging payment reduction policy proposed for the CY 2006 OPPS (70 FR 68707 through 68708), several commenters requested that we postpone implementation until we performed further analyses and were able to find more substantial, hospital-based data to support the 50-percent payment reduction rather than base the policy on MPFS data. The commenters argued that, unlike a relative value unit (RVU) estimate of the total resources associated with a single service for the MPFS, the OPPS cost-based methodology already incorporates the efficiencies of performing multiple procedures during the same session and that median cost estimates for single procedures reflect these savings. Specifically, an imaging CCR consists of the labor and allocated capital and overhead costs for all imaging provided in a department specified by each hospital on its cost report, divided by the total charges for all imaging services provided. In short, commenters stated that because the OPPS cost estimates used for setting the OPPS payment rates for imaging services already reflect costs for a department in general, the CCR used to adjust charges to costs currently incorporated savings from the imaging efficiencies associated with multiple procedures provided in a single session. By applying this CCR to every charge on a claim, the commenters noted that CMS averages multiple imaging efficiencies for all imaging services across all service costs estimated with the departmental CCR. At its August 2005 meeting, the APC Panel heard this and other arguments and recommended that CMS postpone implementation of the policy for a year in order to gather more data on the impact of the proposed changes.

In the CY 2006 OPPS final rule with comment period (70 FR 68516), we acknowledged that, based on our analysis of how hospitals report charges and costs for diagnostic radiology services, it may be correct that the median costs from hospital claims data for the imaging services in the 11 families proposed for the reduction policy already reflect reduced median costs based, in part, on hospitals' provision of multiple imaging services in a single session. However, we expressed concern that the marginal effect of imaging efficiencies on a given CCR may be negligible, thereby underestimating the impact of multiple imaging efficiencies, especially where hospitals reported all diagnostic radiology services in one cost center and did not split the costs and charges for advanced imaging with CT, MRI, or ultrasound into separate cost centers. Because efficiencies are inherent in our cost methodology, our analysis did not provide a definitive answer regarding how much, on average, the OPPS median costs for single imaging services in the 11 families are reduced due to existing hospital efficiencies related to multiple services provided in a single session. Accordingly, we did not implement a multiple imaging payment reduction policy for the OPPS in CY 2006 (a modified MPFS multiple imaging payment reduction policy was implemented with a 25-percent reduction for certain second and subsequent imaging services for CY 2006, and that same reduction policy currently remains in effect under the MPFS). In the CY 2006 OPPS final rule with comment period (70 FR 68707 through 68708), we stated that, depending upon the results of future

analyses, we might revisit this issue and propose revisions to the structure of our payment rates for imaging procedures in order to ensure that those rates properly reflect the relative costs of initial and subsequent imaging procedures. Since publication of the CY 2006 OPPS final rule with comment period, MedPAC has encouraged us to continue our analyses in order to improve payment accuracy for imaging services under the OPPS, including considering adoption of a multiple procedure payment reduction policy.

In preparation for the CY 2009 OPPS proposed rule, we revisited the issue of how we could improve the accuracy of OPPS payment for multiple imaging procedures and incorporate the lower marginal cost for conducting second and subsequent imaging procedures in the same imaging session. As already noted, for CY 2008, we developed a composite APC methodology to provide a single payment for two or more major independent procedures that are typically performed together during a single operative session and that result in the provision of a complete service (72 FR 66650 through 66652). The composite APCs for LDR prostate brachytherapy services and cardiac electrophysiologic evaluation and ablation services discussed in sections II.A.2.e.(2) and (3), respectively, of this final rule with comment period are classic examples. Providing one payment for an entire session encourages hospitals to closely evaluate the resources they use for all components of the composite service in order to improve their payment relative to the costs of performing the composite service. We decided to explore capturing efficiencies for multiple imaging procedures through a composite APC payment methodology when a hospital provides more than one imaging procedure using the same modality during a single session.

We began by reexamining the 11 imaging families of HCPCS codes for contiguous body areas involving a single imaging modality that we had proposed for CY 2006 and that are currently in use under the MPFS for the multiple imaging procedure payment reduction policy. We based this code-specific analysis on the HCPCS codes recognized under the OPPS for the same procedures that are included in the 11 CY 2008 MPFS imaging families, and in addition, we incorporated the 10 HCPCS codes that were proposed for inclusion in these 11 families for the CY 2009 MPFS. We collapsed the 11 MPFS imaging families into 3 OPPS imaging families according to their modality—1 for ultrasound, 1 for CT and CTA, and 1 for MRI and MRA services. These larger OPPS imaging families generally corresponded to the larger APC groups of services paid under the OPPS relative to the service-specific payment under the MPFS. We believed that these larger OPPS imaging families were appropriate because eliminating the contiguous body area concept that is central to the MPFS imaging families should not significantly limit potential efficiencies in an imaging session. For example, we would not expect second and subsequent imaging procedures of the same modality involving noncontiguous body areas to require duplicate facility services such as greeting the patient, providing education and obtaining consent, retrieving prior exams, setting up an intravenous infusion, and preparing and cleaning the room, any more than second and subsequent imaging procedures of the same modality on contiguous body areas. The contiguous body area concept was a component of MedPAC's recommendation for reducing physician payment, but we believed it was less appropriate for a single, session-based OPPS composite imaging payment. In addition, we estimated that using these collapsed OPPS families would add only 12 percent additional claims to those eligible for composite payment relative to using the 11 MPFS imaging families, suggesting that under the OPPS, multiple imaging claims were within the same imaging modality and involved contiguous body areas the vast majority of the time. Nevertheless, the three OPPS imaging families would allow us to capture additional claims for payment under an imaging composite payment methodology.

Another unique aspect of imaging procedures for OPPS ratesetting, in general, is their inclusion on our bypass list and contribution to creating ''pseudo'' single claims, particularly those procedures that are specifically performed without the administration of contrast. Our creation of ''pseudo'' single claims from multiple procedure claims is discussed in section II.A.1.b. of this final rule with comment period. In beginning to model these potential multiple imaging composite APCs for the CY 2009 OPPS/ASC proposed rule, we noted that there would be overlap between the bypass list and noncontrast imaging HCPCS codes that are included in the three OPPS imaging families. The bypass process removes any line-item for a bypass HCPCS code, irrespective of units, from multiple procedure claims. The line-item information is used to make at least one ''pseudo'' single bill and the line-items remaining on the claim are split by date and reassessed for single bill status. To model the median costs for the potential multiple imaging composite APCs for the CY 2009 OPPS/ASC proposed rule, we removed any HCPCS codes in the OPPS imaging families that overlapped with codes on our bypass list 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 proposed multiple imaging composite APC median costs appeared in Table 7 of the CY 2009 OPPS/ASC proposed rule. 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 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. For the CY 2009 OPPS/ASC proposed rule, our last step after processing all claims through the ''pseudo'' single process was to make line-items for HCPCS codes in the OPPS imaging families remaining on multiple procedure claims with one unit of the imaging HCPCS code and no other imaging services in the families into ''pseudo'' single bills for use in calculating the median costs for sole imaging services.

One final requirement of our assessment of multiple imaging composite APCs was our expansion of the OPPS families for the three modalities—ultrasound, CT and CTA, and MRI and MRA—into five composite APCs to accommodate the statutory requirement in section 1833(t)(2)(G) of the Act, that the OPPS provide payment for imaging services provided with contrast and without contrast through separate payment groups. The ultrasound studies proposed for inclusion in the multiple imaging composite policy do not utilize contrast and thus this family constituted a single composite APC. However, we had to split the families for CT and CTA, and MRI and MRA, into two separate composite APCs each to reflect whether the procedures were performed with or without contrast. We examined the HCPCS codes on our ''single session'' claims and, if the claim had at least one

HCPCS code that was performed with contrast, we classified the ''single session'' bill as ''with contrast.'' For both CT and CTA, and MRI and MRA, some claims classified as ''with contrast'' contained one or more ''without contrast'' HCPCS code. We then recalculated the median costs for the standard (sole service) imaging APCs based on single and ''pseudo'' single bills and the imaging composite APC median costs based on appropriate ''single session'' bills with multiple imaging procedures.

For the CY 2009 OPPS/ASC proposed rule, we were able to identify 1.7 million ''single session'' claims out of an estimated 3 million potential composite cases from our ratesetting claims database to calculate the proposed median costs for the 5 OPPS multiple imaging composite APCs. We specifically noted that the proposed CY 2009 payment rates for multiple imaging services provided during the same session and within the same OPPS imaging family were based entirely on median costs derived empirically from OPPS claims and Medicare cost report data.

In general, we found that the per procedure median cost for each of the multiple imaging procedures performed during a single session, and reflected in the composite APC median costs, was modestly less than the sole service median cost when only one imaging procedure was performed during a single session, as reflected in the median cost of the standard (sole service) imaging APCs (that is, those imaging services that would not have qualified for payment through a multiple imaging composite APC under the proposed composite methodology). We also noticed that the proposed CY 2009 median costs for the standard (sole service) imaging APCs increased slightly compared to the median costs that we would calculate using the current OPPS imaging service payment policy. These variations in median costs were consistent with our expectations. Because the OPPS cost-based payment weight methodology estimates a standard cost per imaging procedure for each hospital, these results suggested that the imaging composite ''single session'' claims disproportionately represented services furnished by more efficient providers that frequently performed more than one imaging procedure during a single session. The lower cost claims also may have included more providers that reported costs and charges for nonstandard cost centers for advanced imaging on their Medicare hospital cost reports.

In light of these findings, we determined that a proposal to revise our methodology for paying for multiple imaging procedures was warranted because the current OPPS policy of providing a full APC payment for each imaging procedure on a claim, regardless of how many procedures are performed during a single session using the same imaging modality, neither reflects nor promotes the efficiencies hospitals can achieve when they perform multiple imaging procedures during a single session, as seen in the claims data.

Therefore, in the CY 2009 OPPS/ASC proposed rule (73 FR 41450 through 41451), we proposed to utilize the three OPPS imaging families discussed above, incorporating statutory requirements to differentiate OPPS payment for imaging services provided with contrast and without contrast as required by section 1833(t)(2)(G) of the Act, to create five multiple imaging composite APCs for payment in CY 2009. The proposed APCs were: 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 calculated the proposed median costs for these APCs using CY 2007 claims data by isolating ''single session'' claims with more than one imaging procedure within a family as discussed above. Unlike our CY 2006 proposal where we would have applied a 50-percent payment reduction for second and subsequent imaging procedures comparable to the proposed MPFS policy, the CY 2009 OPPS proposal calculated the composite APC payment amounts empirically from estimated costs on claims for multiple imaging procedures provided in a single session. This proposed composite methodology for multiple imaging services paralleled the payment methodologies that we proposed for other composite APCs under the CY 2009 OPPS. Table 8 of the CY 2009 OPPS/ASC proposed rule presented the HCPCS codes comprising the three OPPS imaging families and five composite APCs that would be created under this proposal for CY 2009, along with the proposed median costs upon which the proposed payment rates for these composite APCs were based.

During the August 2008 APC Panel meeting, the APC Panel recommended that CMS work with stakeholders to review the proposed multiple imaging composite APCs and to assess the potential impact of the proposal on Medicare beneficiaries affected by trauma or cancer.

Comment: Some commenters stated that the proposed multiple imaging composite payment methodology would improve the accuracy of OPPS payment for imaging services and that CMS should implement the policy as proposed. In particular, MedPAC stated that the proposed multiple imaging composite APCs are consistent with larger payment bundles and should increase hospitals' incentives to furnish care efficiently. MedPAC further asserted that the multiple imaging composite policy could serve as a starting point for creating more comprehensive payment bundles that reflect encounters or episodes of care.

However, many commenters urged CMS to perform additional data analyses of CY 2007 claims with multiple imaging services and, depending on the results, modify the final policy to ensure sufficient payments are made to hospitals for providing an appropriate number of imaging services. In particular, commenters indicated that the proposed policy could have a disproportionately negative effect on cancer centers and trauma units, where patients frequently require more than two imaging services and hospitals have limited flexibility to gain greater efficiencies. The commenters also questioned the adequacy of the proposed multiple imaging composite payment rates for sessions involving three or more or four or more procedures, particularly in the case of CT and CTA procedures, expressing general concern that the proposed payment rates would limit beneficiary access to imaging services. According to these commenters, the proposed policy could create incentives for hospitals to require patients who need more than two imaging procedures to return for additional visits if the costs for sessions in which more than two procedures are performed far exceed the multiple imaging composite APC payment rates. Some commenters also requested that CMS thoroughly evaluate the impact of the multiple imaging composite APCs after the policy has been implemented to ensure that hospitals are being adequately compensated for providing multiple imaging services. Other commenters remarked generally that CMS should proceed cautiously as it expands service bundling, should accompany composite proposals with data and a clear and transparent description of the data-generating process, and should not implement additional composite methodologies until adequate data are available to evaluate the effectiveness

and impact on beneficiary access to care of the composite policies implemented in CY 2008.

In order to address perceived payment inadequacies or incentives for hospitals to require patients to return on separate days for multiple imaging services, the commenters suggested a variety of alternative approaches to the proposed multiple imaging composite payment methodology, such as a multiple imaging payment reduction policy for second and subsequent imaging procedures, additional composite APCs for sessions involving three or more imaging procedures, or an exemption from composite payment for multiple imaging services provided to cancer or trauma patients. One commenter specifically recommended two new composite APCs for CT scans of the chest, abdomen, and pelvis with and without contrast.

Some commenters, however, opposed the implementation of any payment policy to account for the efficiencies of multiple imaging procedures provided during the same session, arguing that the OPPS cost-based methodology already incorporates the efficiencies of performing multiple procedures during the same session. They believed that adding a composite policy essentially ''double counts'' imaging efficiencies. One commenter opposed the policy because, according to the commenter, hospitals do not have the option of refusing to provide services that are ordered by a physician, and cannot control the cost of providing a service in relationship to the cost of the equipment. Another commenter noted that MRI equipment costs are fixed in the short term.

Response: We have reviewed all of the public comments we received on the proposed multiple imaging composite methodology, and we have decided to finalize our proposal to provide a single composite payment each time a hospital bills more than one procedure from an imaging family on a single date of service for CY 2009. We appreciate the commenters' thoughtful observations and suggestions.

In response to the commenters' concerns about the adequacy of the proposed composite APC payment rates for sessions involving more than two imaging procedures, we analyzed data from the CY 2007 claims from which the median costs used to calculate those payment rates were calculated. We found that the vast majority of CY 2007 claims used for ratesetting included two procedures, ranging from 73 percent of multiple imaging procedure claims for APC 8008, to 97 percent of multiple imaging procedure claims for APC 8004. We do not believe that, in aggregate, OPPS payment for multiple imaging services will be inadequate under the multiple imaging composite payment methodology, even considering the minority of cases in which hospitals provide more than two imaging procedures on a single date of service. The median costs upon which the payment rates for the multiple imaging composite APCs are based are calculated using CY 2007 claims that would have qualified for composite payment, including those with only two imaging procedures and those with substantially higher numbers of imaging procedures. Payment based on a measure of central tendency is a principle of any prospective payment system. In some individual cases payment exceeds the average cost and in other cases payment is less than the average cost. On balance, however, payment should approximate the relative cost of the average case, recognizing that, as a prospective payment system, the OPPS is a system of averages.

Furthermore, the purpose of the composite payment methodology overall is to establish incentives for efficiency through larger payment bundles. Based on our observations of only small to moderate percentages of single sessions with three or more imaging procedures, we do not believe it would be appropriate to create additional multiple imaging composite APCs for sessions involving more than two or three imaging procedures. The various suggestions by some commenters regarding the creation of additional composite APCs for payment of three or more procedures or for specific combinations of scans all would remove some of the efficiency incentives associated with a single bundled payment and would make the multiple imaging policy more closely resemble standard payment for single procedures. Additional composite APCs would not be consistent with encouraging value-based purchasing under the OPPS. We note that the OPPS does have an outlier policy for cases involving extremely high costs, as discussed in section II.F. of this final rule with comment period.

We also do not believe that the multiple imaging composite payment methodology will inhibit beneficiary access to imaging services, because the policy will result in only relatively modest payment redistributions in the short term. We estimate that total payment impact among classes of hospitals attributable to changes in imaging payment will be relatively small, and we expect that the multiple imaging composite policy will redistribute about 0.4 percent of total OPPS payment. We believe this policy does more to redesign incentives in providing imaging services than to significantly reduce imaging payment to hospitals for CY 2009.

Further, we do not agree with some commenters that the multiple imaging composite payment methodology would result in hospitals requiring patients who need more than two imaging procedures to return for additional visits. We do not believe that, in general, hospitals would routinely and for purposes of financial gain put patients at unnecessary risk of harm from radiation or contrast exposure, or inconvenience them or risk lack of timely follow up to the point of making them return to the hospital on separate days to receive medically necessary diagnostic studies. However, we note that we do have the capacity to examine our claims data for patterns of fragmented care. If we were to find a pattern in which a hospital appears to be fragmenting care across multiple days, we could refer it for review by the Quality Improvement Organizations (QIOs) with respect to the quality of care furnished, or for review by the Program Safeguard Contractors of claims against the medical record, as appropriate to the circumstances we found.

In addition, we explored data from the CY 2007 claims from which the median costs used to calculate the multiple imaging composite APC payment rates were calculated in response to comments that the policy would have a disproportionate effect on cancer centers and trauma units and the recommendation by the APC Panel at its August 2008 meeting, which we are accepting. An analysis of diagnosis codes present on the CY 2007 multiple imaging ''single session'' claims did show more variability in the number of scans for cancer patients compared to other types of patients, consistent with commenters' concerns. We saw that, for several of the more commonly reported cancer diagnoses, more than half of the patients received more than two imaging procedures, while lower proportions of other types of patients received more than two imaging procedures on a single date of service. We did not observe the same pattern for trauma diagnoses. We do not believe that the higher rate of variability that we observed in the number of scans cancer patients receive was so extreme, however, that the mix of services hospitals provide to patients with diagnoses other than cancer would not balance out higher numbers of scans for cancer patients.

We do not have a current list of cancer centers other than those held permanently harmless under section 1833(t)(7)(D)(ii) of the Act or a current list of hospitals with significant trauma units in order to assess outcomes for these particular classes of hospitals. However, as noted above, we do not estimate significant redistributions among hospitals as a result of this policy. Further, the goal of introducing a single composite payment for any multiple imaging session is to encourage hospitals to consider their patterns of service provision in general, and not payment per patient. Therefore, we do not believe that the multiple imaging composite methodology will result in disproportionate effects on either hospitals with cancer centers or trauma units, and we do not agree with some commenters that it would be appropriate to exempt services provided to cancer and trauma patients from the multiple imaging composite APC payment policy. We see no justification for paying differently for the same imaging services according to patient diagnosis or care setting, because we believe that most hospitals demonstrate sufficient variability in the number of imaging procedures they provide to a single patient on the same day that it is unlikely that certain hospitals would disproportionately experience negative financial effects from the multiple imaging composite APC payment policy.

We also do not agree that the multiple imaging composite APCs are unnecessary, as some commenters argued, because the OPPS cost-based methodology already incorporates the efficiencies of performing multiple imaging procedures during the same session. While we agree that efficiencies due to multiple imaging procedures are generally reflected in hospitals' CCRs used to develop costs, we believe that the advantage of a composite methodology for imaging services is that it allows us to use naturally occurring multiple procedure claims to calculate the median costs for sessions involving multiple procedures, rather than using single procedure claims which do not reflect as accurately how hospitals provide care in those instances. The lower per case median cost for multiple imaging services suggests that hospitals providing more multiple imaging services generally have lower costs. We note that a small increase in the median cost of standard (sole service) APCs accompanied our lower multiple imaging composite APC median costs. The multiple imaging policy does not ''double count'' efficiencies for imaging; rather, it more accurately estimates the costs of single versus multiple imaging sessions.

We believe that we are proceeding with an appropriate level of caution, as several commenters recommended, by developing one new composite APC policy for CY 2009. We did not receive any comments to the CY 2009 OPPS/ASC proposed rule indicating there were access problems resulting from the implementation of composite APCs in CY 2008, which was consistent with our expectations given the composite methodology improves the accuracy of the OPPS payment rates by utilizing more complete and valid claims in ratesetting. With regard to providing data and a transparent methodology, we point out that we make our claims data available to the public, and we discuss our calculation of these multiple imaging composite APC payment rates in both this section and in section II.A.1. of the CY 2009 OPPS/ASC proposed rule (73 FR 41423 through 41425). We also have a claims accounting narrative available under supporting documentation for this final rule with comment period on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/*.

We disagree with commenters who asserted that we should not implement the multiple imaging composite methodology because hospitals do not have the option of refusing to provide services that are ordered by a physician, and cannot control the cost of providing a service in relationship to the cost of the equipment. While physicians, rather than hospital staff, may order specific services for patients, hospitals decide what services they will and will not furnish, and how they will furnish those services. We also disagree that fixed capital equipment costs are a deterrent to implementing a multiple imaging composite payment methodology. As discussed earlier, data analyses performed for the CY 2009 OPPS/ASC proposed rule showed that some hospitals are more efficient than other hospitals when providing multiple imaging services. A prospective payment system sets payments based on a median or average cost to encourage providers to carefully consider their costs of providing services, and in any individual case payment may exceed the average or median cost. We would expect less efficient hospitals to construct ways to become more efficient, such as negotiating lower costs on equipment, even if they do not have the latitude to perform fewer imaging services.

Comment: Some commenters urged CMS to standardize cost reporting for both advanced imaging procedures and other problematic cost centers before it makes any methodological changes to OPPS payment methodologies, including a composite policy for multiple imaging procedures. According to the commenters, additional efficiencies can only be gained from improved accuracy in cost reporting for diagnostic radiology services, including use of several standard cost centers for diagnostic imaging services. The commenters were concerned that observed efficiencies in the multiple imaging composite median costs are the result of inaccurate cost report data only and do not reflect true efficiencies from multiple imaging services provided during a single session. These commenters stated that the implementation of separate cost centers for CT and MRI procedures, as recommended in the July 2008 report by RTI entitled, ''Refining Cost to Charge Ratios for Calculating APC and DRG Relative Payment Weights,'' would provide much more accurate charge and cost data for these imaging modalities, and that the efficiencies associated with providing multiple imaging procedures in a single session may only be discernable once these data are available. The commenters recommended that CMS analyze claims data for a 2 to 3 year period following cost reporting changes before considering a multiple imaging composite payment methodology.

Response: As discussed in section II.A.1.c.(2) of this final rule with comment period, we agree with commenters that improved and more precise cost reporting would improve OPPS payment accuracy. Even if we were to make changes to create new diagnostic radiology cost centers for CT and MRI procedures as recommended by the commenters for future years, it would be several years after initial implementation before data would be available to reevaluate OPPS payment rates for imaging services. In the meantime, we see no reason not to move forward with other changes in OPPS payment policies, such as the multiple imaging composite APC payment methodology, that could improve the accuracy of OPPS payment rates and promote efficiency among hospitals. The most recent hospital cost report data are the best and most consistent estimate of relative costs that we have available to us for all hospitals for all hospital services. We will continue to use these data to estimate APC median costs. Our goal in creating this new payment structure is to encourage long-term efficiencies in the provision of

multiple imaging services. Should improved, revised cost report data become available for CT and MRI procedures, our composite methodology would automatically incorporate that additional precision into the multiple imaging composite APC median cost estimates.

Comment: Several commenters expressed concern that the proposed composite payment methodology for multiple imaging procedures may not comply with the statutory requirement in section 1833(t)(2)(G) of the Act that the OPPS provide payment for imaging services furnished with and without contrast through separate payment groups. They requested that CMS not use data from services performed without contrast to set the payment rates for the ''with contrast'' composite APCs, arguing that the inclusion of cost data from procedures performed without contrast in the median cost calculation for the ''with contrast'' composite APCs may fail to capture the full costs of imaging services provided with contrast agents. A handful of commenters sought clarification about whether CMS had included ''single session'' claims that incorporated ''without contrast'' HCPCS codes in the ''with contrast'' composite. Another commenter requested that the more costly CT and MRI studies performed without contrast and then followed by contrast, and described by a single combination CPT code, be paid through separate composite APCs. According to the commenter, the inclusion of these procedures with other ''with contrast'' studies would cause their median payment level to decrease.

Response: We believe that the composite payment methodology for multiple imaging procedures complies with the statutory requirement in section 1833(t)(2)(G) of the Act that the OPPS provide separate payment groups for imaging services provided with and without contrast. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66650), section 1833(t)(1)(B) of the Act permits us to define what constitutes a covered HOPD ''service'' for purposes of payment under the OPPS, and we have not restricted a ''service'' to a single HCPCS code. Defining the service paid under the OPPS by combinations of HCPCS codes for procedures that are commonly performed in the same encounter and that result in the provision of a complete service enables us to use more claims data and establish payment rates that we believe more appropriately capture the costs of services paid under the OPPS. Consistent with our statutory flexibility to define what constitutes a service under the OPPS, we have redefined an imaging service for purposes of the multiple imaging composite methodology as a ''single session'' involving multiple imaging procedures within an imaging family performed on the same date of service. Furthermore, if a contrast agent is provided to a Medicare beneficiary as part of any imaging procedure furnished during that single imaging session, then we have defined that session as a ''with contrast'' imaging session to allow for payment through a separate group from a ''without contrast'' single imaging session.

Therefore, in order to calculate the median costs for the multiple imaging composite APCs, we designate an entire session as a ''with contrast'' service and use the claim to calculate the median cost for the ''with contrast'' composite APC when at least one of the imaging procedures within an imaging family performed on the same date of service involves contrast. If none of the imaging procedures within an imaging family performed on the same date of service involve contrast, we designate the entire session a ''without contrast'' service and use the claim to calculate the median cost for the ''without contrast'' composite APC.

The statutory requirement that we create separate payment groups to classify imaging procedures performed with contrast and without contrast allows us to recognize that imaging services involving contrast require different hospital resources than imaging services performed without contrast. As shown in Table 8 below, the median costs upon which payment rates are calculated for the ''with contrast'' composite APCs (APC 8006 and APC 8008) are higher than the median costs for the ''without contrast'' composite APCs (APC 8005 and APC 8007). We believe that when multiple imaging services are provided in a single imaging session and only one of the studies uses contrast, hospitals still incur many of the same costs as they would incur if all of the studies used contrast, such as a screening by hospital staff for patient allergies, the establishment of venous access, and the initiation of necessary monitoring. As such, we would not expect that the costs of sessions involving a ''with contrast'' procedure along with other ''with contrast'' procedures in the same family would differ significantly from the costs of sessions involving a ''with contrast'' procedure and procedures that do not involve contrast. Our analysis of the CY 2007 claims data used to calculate the median costs for the multiple imaging composite APCs supported this argument. If we were to remove all ''single session'' claims that included procedures both with contrast and without contrast from the median cost calculation of the two ''with contrast'' composite APCs, the impact on the APC median costs would be negligible—the median cost for APC 8006 would increase by less than 1 percent, and the median cost for APC 8008 would increase by only 4 percent.

In addition, we do not believe it would be appropriate to create a separate composite APC for payment of CT or MRI procedures performed without contrast and then followed by contrast, as described by a single combination CPT code. In effect, these codes already describe a multiple imaging session—a ''without contrast'' imaging service followed by a ''with contrast'' imaging service. This is comparable to some of the other ''single session'' claims in the CT/CTA and MRI/MRA ''with contrast'' composite APCs (APC 8006 and APC 8008, respectively), in that these composite APCs incorporate in some ''single session'' claims certain ''without contrast'' imaging services. We believe that our definition of a single session with contrast as including the costs associated with providing a contrast agent for any one or more individual procedures appropriately places these combination CPT codes in APCs 8006 and 8008 and meets the statutory requirements.

Finally, we agree with several commenters that APC 8004 includes only ultrasound studies performed without contrast. Should we revise the HCPCS codes in APC 8004 to include ultrasound imaging services performed with contrast in the future, we would create a new composite APC for ''with contrast'' ultrasound procedures to comply with section 1833(t)(2)(G) of the Act.

In summary, we believe the payment differential between the ''with contrast'' composite APCs and the ''without contrast'' composite APCs is appropriate, regardless of whether or not the other imaging procedures provided within the same session as an imaging procedure performed with contrast are also performed with contrast. We believe we are in full compliance with the statutory requirement that we create groups of covered OPPS services that utilize contrast agents and those that do not utilize contrast agents by redefining multiple imaging services provided in one encounter as a ''single session'' in which more than one procedure from an imaging family is provided on the same date of service and assigning ''with

contrast'' composite APCs when at least one of the procedures involves contrast.

Comment: One commenter stated that, before implementing the multiple imaging composite policy, CMS should consult with relevant stakeholders about which CPT codes should be subject to the policy. The commenter also urged CMS to provide hospitals with instructions to continue coding for packaged and bundled services to ensure adequate data collection. Another commenter stated that CMS should delay implementation of the multiple imaging composite policy to allow hospitals that use the charging of single CPT codes to determine staff levels and productivity to adjust to the proposed changes. One commenter recommended that CMS work with the AMA to create new CPT codes that describe combined procedures so that providers could use those codes when they provide multiple imaging services in a single session. The commenter argued that utilization of such codes would be easier for providers and would facilitate the capturing of charge data that could be used to create new APCs or payment policies that reflect economies of scale for combined procedures reported through claims data.

Response: Consistent with our standard process for securing the views of stakeholders through the rulemaking cycle, we published a detailed account of the multiple imaging composite payment methodology proposed for CY 2009 in the CY 2009 OPPS/ASC proposed rule (73 FR 41447 through 41451) and requested comment. Table 8 of the CY 2009 OPPS/ASC proposed rule presented the HCPCS codes comprising the three OPPS imaging families and five composite APCs that would be created under the multiple imaging composite proposal for CY 2009. We did not receive any comments on the particular imaging HCPCS codes or the families of codes we proposed for composite payment. Therefore, we will apply the multiple imaging composite methodology to the HCPCS codes listed in Table 8 below, for CY 2009. These HCPCS codes are assigned status indicator ''Q3'' in Addendum B to this final rule with comment period to identify their status as potentially payable through a composite APC. Their composite APC assignments are identified in Addendum M to this final rule with comment period.

We continue to encourage hospitals to report the HCPCS codes and associated charges for all services they provide, taking into consideration all CPT, CMS, and local Medicare contractor instructions, whether payment for those HCPCS codes is packaged or separately provided. We note that the multiple imaging composite APC payment policy should have no operational impact on hospital billing practices, because hospitals should continue reporting the same HCPCS codes they currently use to report imaging procedures. The I/OCE will assess claims to determine whether a composite APC or a standard (sole service) imaging APC should be assigned. We believe that an advantage of the multiple imaging composite methodology is that it can improve the accuracy of OPPS payment without imposing burdens on hospitals to use different codes or change the way they report services.

We do not agree with the commenter that it would be necessary to create new CPT codes that describe combined services to ease the burden of hospital billing and improve claims data for ratesetting. As discussed earlier, certain combination CPT codes, specifically those single codes that describe imaging procedures without contrast and then followed by contrast, already allow for hospitals to report commonly performed combinations of imaging procedures in one anatomic area using a single CPT code. Hospitals can continue to use existing codes to report combined services by reporting multiple HCPCS codes, and for ratesetting, we use the charges reported to us by hospitals for combined services to calculate composite APC payment rates.

Comment: The commenters asked for clarifications and offered recommendations regarding how the multiple imaging composite policy would be implemented. A few commenters also requested that CMS clarify what constitutes a ''single session'' and provide guidance on how hospitals are to bill and receive payment for multiple imaging procedures provided on the same date of service but during different encounters. According to the commenters, a composite payment would not be appropriate in such cases because facility resources are expended each and every time a patient is seen for a separate procedure. Some commenters suggested CMS address these cases by allowing the use of the ''59'' modifier to signify a distinct procedural service and implementing I/OCE logic that would not assign composite payment in those instances. Other commenters stated that hospitals would not track whether multiple scans took place during single or separate sessions on the same day, and asked that CMS provide standard (sole service) APC payment when hospitals provide imaging services that would otherwise be subject to the composite methodology on the same date of service but at different times.

Response: A single imaging session for purposes of the multiple imaging composite APC payment policy involves more than one procedure within the same family provided on a single date of service. We believe that composite payment is appropriate even when procedures are provided on the same date of service but at different times, because hospitals do not expend the same facility resources each and every time a patient is seen for a distinct imaging service in a separate imaging session. In most cases, we expect that patients in these circumstances would receive imaging procedures at different times during a single prolonged hospital outpatient encounter. The efficiencies that may be gained from providing multiple imaging procedures during a single session are achieved in ways other than merely not having to reposition the patient. For example, a patient who has two MRI procedures three hours apart during a single hospital outpatient encounter would not have to be registered again, and hospital staff might not have to explain the procedure in detail prior to the second scan. In the case of multiple procedures involving contrast that are provided at different times during a single hospital outpatient encounter, establishment of new intravenous access for the second study would not be necessary. Even if the same level of efficiencies could not be gained for multiple imaging procedures performed on the same date of service but at different times, we expect that any higher costs associated with these cases would be reflected in the claims data and cost reports we use to calculate the median costs for the multiple imaging composite APCs, and therefore, in the payment rates for the multiple imaging composite APCs. We do not believe it is necessary or appropriate for hospitals to report imaging procedures provided on the same date of service but during different encounters any differently than they would report imaging procedures performed consecutively with no time in between.

In all cases, hospitals that furnish more than one imaging procedure to a Medicare beneficiary in the HOPD on the same date of service must bill all imaging services on the same claim. We expect to carefully monitor any changes in billing practices on a service-specific and hospital-specific basis to determine whether there is reason to request that QIOs review the quality of care furnished or to request that Program Safeguard Contractors review the claims against the medical record.

Comment: Several commenters asked whether the multiple imaging composite policy would affect application of section 5102(b)(1) of the Deficit Reduction Act (DRA), which requires CMS to cap the technical component of the MPFS payment amount by the OPPS payment amount for certain imaging procedures. One commenter asked if the savings from this proposal are budget neutral.

Response: The payment comparison for the DRA cap on the MPFS technical component payment for imaging services will continue to be made between the applicable MPFS technical component payment and the payment for the standard (sole service) imaging APC payment for services subject to the cap, even if multiple MPFS imaging services subject to the DRA cap are provided in one imaging session.

Modest imaging savings from the multiple imaging composite methodology of 0.4 percent are budget neutral and are redistributed to other services paid under the OPPS for CY 2009.

In summary, after consideration of the public comments received, we are adopting our CY 2009 proposal, without modification, to utilize the three OPPS imaging families discussed above in this section, incorporating statutory requirements to differentiate OPPS payment for imaging services provided with contrast and without contrast as required by section 1833(t)(2)(G) of the Act, to create five multiple imaging composite APCs for payment in CY 2009. The multiple imaging composite APCs for 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). The composite APCs have status indicators of ''S,'' signifying that payment for the APC is not reduced when it appears on the same claim with other significant procedures.

We will provide one composite APC payment each time a hospital bills more than one procedure described by the HCPCS codes in an OPPS imaging family displayed in Table 8 below, on a single date of service. If the hospital performs a procedure without contrast during the same session as at least one other procedure with contrast using the same imaging modality, then the hospital will receive payment for the ''with contrast'' composite APC. A single imaging procedure, or imaging procedures reported with HCPCS codes assigned to different OPPS imaging families, will be paid according to the standard OPPS methodology through the standard (sole service) imaging APCs to which they are assigned in CY 2009. Hospitals will continue to use the same HCPCS codes to report imaging procedures, and the I/OCE will determine when combinations of imaging procedures qualify for composite APC payment or map to standard (sole service) APCs for payment. We will 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.

To calculate the final rule median costs for the five multiple imaging composite APCs, we removed any HCPCS codes in the OPPS imaging families that overlapped with codes on our bypass list 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 multiple imaging composite APC median costs appear in Table 9 below. (We refer readers to section II.A.1.b. of this final rule with comment period for further discussion of how we treat claims with HCPCS codes in the OPPS imaging families that are also on the 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 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. This enhanced our proposed rule methodology of only identifying line-item costs for HCPCS codes in the OPPS imaging families remaining on multiple procedure claims with one unit of the imaging HCPCS code and no other imaging services in the families as potential ''pseudo'' single bills for use in calculating the median costs for sole imaging services. For this final rule with comment period, we not only made ''pseudo'' single bills out of line-items for the HCPCS codes in the OPPS imaging families overlapping with the HCPCS codes on the bypass list, which appear in Table 9 below, but we reassessed each claim after removing these line-items in order to see 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.'' In particular, this change significantly increased the number of single bills available for APC 0274 (Myelography) for this final rule with comment period. We were able to identify 1.8 million ''single session'' claims out of an estimated 3 million potential composite cases from our ratesetting claims database, or over half of all eligible claims, to calculate median costs for the 5 final CY 2009 OPPS multiple imaging composite APCs.

TABLE 8—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1—Ultrasound	
Final CY 2009 APC 8004 (Ultrasound Composite)	**Final CY 2009 Approximate APC Median Cost = $188**
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.

TABLE 8—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

76857	Us exam, pelvic, limited.
Family 2—CT and CTA with and without Contrast	
Final CY 2009 APC 8005 (CT and CTA without Contrast Composite)*	**Final CY 2009 Approximate APC Median Cost = $406**
0067T	Ct colonography;dx.
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.
Final CY 2009 APC 8006 (CT and CTA with Contrast Composite)	**Final CY 2009 Approximate APC Median Cost = $621**
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.
75635	Ct angio abdominal arteries.
Family 3—MRI and MRA with and without Contrast	
Final CY 2009 APC 8007 (MRI and MRA without Contrast Composite)*	**Final CY 2009 Approximate APC Median Cost = $695**
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.

TABLE 8—OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS—Continued

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.
Final CY 2009 APC 8008 (MRI and MRA with Contrast Composite)	**Final CY 2009 Approximate APC Median Cost = 968**
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'' 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 8005.

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

TABLE 9—OPPS IMAGING FAMILY SERVICES OVERLAPPING WITH HCPCS CODES ON THE CY 2009 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.

TABLE 9—OPPS IMAGING FAMILY SERVICES OVERLAPPING WITH HCPCS CODES ON THE CY 2009 BYPASS LIST—Continued

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. Calculation of OPPS Scaled Payment Weights

Using the APC median costs discussed in sections II.A.1. and 2. of this final rule with comment period, we calculated the final relative payment weights for each APC for CY 2009 shown in Addenda A and B to this final rule with comment period. 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 visit APCs. We selected APC 0606 as the base because APC 0606 was the middle level clinic visit APC (that is, Level 3 of five levels). We had historically used the median cost of the middle level clinic visit APC (that is APC 0601 through CY 2006) to calculate unscaled weights because mid-level clinic visits were among the most frequently performed services in the hospital outpatient setting. Therefore, for CY 2009, to maintain consistency in using a median for calculating unscaled weights representing the median cost of some of the most frequently provided services, we proposed to continue to use the median cost of the mid-level clinic visit APC, proposed APC 0606, to calculate unscaled weights. Following our standard methodology, but using the proposed CY 2009 median cost for APC 0606, for CY 2009 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 unscaled relative payment weight for each APC. The choice of the APC on which to base the 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 estimated aggregate payments under the OPPS for CY 2009 are neither greater than nor less than the estimated aggregate payments that would have been made without the changes. To comply with this requirement concerning the APC changes, we proposed to compare aggregate payments using the CY 2008 scaled relative weights to aggregate payments using the CY 2009 unscaled relative weights. Again this year, we included payments to CMHCs in our comparison. Based on this comparison, we adjusted the unscaled relative weights for purposes of budget neutrality. The unscaled relative payment weights were adjusted by a weight scaler of 1.3354 for budget neutrality in the CY 2009 OPPS/ASC proposed rule (73 FR 41452). In addition to adjusting for increases and decreases in weight due to the recalibration of APC medians, the scaler also accounts for any change in the base, other than changes in volume which are not a factor in the weight scaler.

Section 1833(t)(14)(H) of the Act, as added by section 621(a)(1) of Public Law 108–173, 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.'' Section 1833(t)(14) of the Act provides the payment rates for certain ''specified covered outpatient drugs.'' Therefore, the cost of those specified covered outpatient drugs (as discussed in section V. of this final rule with comment period) is included in the budget neutrality calculations for the CY 2009 OPPS.

We did not receive any public comments on the proposed methodology for calculating scaled weights from the median costs for the CY 2009 OPPS. Therefore, we are finalizing our proposed methodology, without modification, including updating of the budget neutrality scaler for this final rule with comment period,

as we proposed. Under this methodology, the final unscaled payment weights were adjusted by a weight scaler of 1.3585 for this final rule with comment period. The final scaled relative payment weights listed in Addenda A and B to this final rule with comment period incorporate the recalibration adjustments discussed in sections II.A.1. and 2. of this final rule with comment period.

4. 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 costs of providing a service or package of services for a particular patient, but with the exception of outlier cases, is adequate to ensure access to appropriate care. Packaging and bundling payment for multiple interrelated services into a single payment create incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment. For example, where there are a variety of supplies that could be used to furnish a service, some of which are more expensive than others, packaging encourages hospitals to use the least expensive item that meets the patient's needs, rather than to routinely use a more expensive item. 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. Finally, packaging payments into larger payment bundles promotes the stability of payment for services over time. Packaging and bundling 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.

Decisions about packaging and bundling payment involve a balance between ensuring some separate payment for individual services and establishing incentives for efficiency through larger units of payment. Over the past several years of the OPPS, greater unpackaging of payment has occurred simultaneously with continued growth in OPPS expenditures as a result of increasing volumes of individual services. In an attempt to address this increase in volume of services, in the CY 2008 OPPS/ASC final rule with comment period, we finalized additional packaging for the CY 2008 OPPS, which included the establishment of four 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) (72 FR 66650 through 66659). HCPCS codes that may be paid through a composite APC if certain composite-specific criteria are met or otherwise may be paid separately are assigned status indicator ''Q'' for CY 2008, and we consider them to be conditionally packaged. We discuss composite APCs in more detail in section II.A.2.e. of this final rule with comment period.

In addition, 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 the seven categories listed below 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: guidance services, image processing services, intraoperative services, imaging supervision and interpretation services, diagnostic radiopharmaceuticals, contrast media, and 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 the HCPCS codes that 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. We finalized our assignment of status indicator ''N'' to those HCPCS codes that we believe are always integral to the performance of the primary modality, so we always package their costs into the costs of the separately paid primary services with which they are billed. Services assigned status indicator ''N'' in CY 2008 are unconditionally packaged. We also finalized our assignment of status indicator ''Q'' to those HCPCS codes that we believe are typically integral to the performance of the primary modality and, in such cases, we package payment for their costs into the costs of the separately paid primary services with which they are usually billed. An ''STVX-packaged code'' describes a HCPCS code whose payment is packaged when one or more separately paid primary services 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 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 HCPCS codes'' assigned status indicator ''Q'' in CY 2008 are conditionally packaged.

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. We note that, in future years as we consider the development of larger payment groups that more broadly reflect services provided in an encounter or episode-of-care, it is possible that we might propose to bundle payment for a service that we now refer to as ''independent.''

An example of a CY 2008 change in the OPPS packaging status for a dependent HCPCS code that is ancillary and supportive is CPT code 61795 (Stereotactic computer-assisted volumetric (navigational) procedure, intracranial, extracranial, or spinal (List separately in addition to code for primary procedure)). CPT code 61795 was assigned separate payment in CY 2007 but its payment is packaged during CY 2008. This service is only performed during the course of a surgical procedure. Several of the surgical procedures that we would expect to be reported in association with CPT code 61795 are assigned to APC 0075 (Level V Endoscopy Upper Airway) for CY 2008. We consider the stereotactic guidance service to be an ancillary and supportive service that may be performed only in the same operative session as a procedure that could otherwise be performed independently of the stereotactic guidance service.

During its March 2008 meeting, the APC Panel recommended that CMS report to the APC Panel at its first CY 2009 meeting the impact of packaging on the net payments for patient care. We will take this recommendation into

consideration and determine which data we can provide at the first CY 2009 APC Panel meeting that would best respond to this recommendation. The APC Panel also recommended that CMS present data at the first CY 2009 APC Panel meeting on usage and frequency, geographic distribution, and size and type of hospitals performing nuclear medicine examinations and using radioisotopes to ensure that access to these services is preserved for Medicare beneficiaries. This recommendation is discussed in more detail in section V.B.2.c. of this final rule with comment period.

Hospitals include charges for packaged services on their claims, and the 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 CPT or CMS provide other guidance. If a HCPCS code is not reported when a packaged service is provided, it can be challenging to track utilization patterns and resource costs.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41453), we proposed to further refine our identification of the different types of conditionally packaged HCPCS codes that were previously all assigned status indicator ''Q'' (Packaged Services Subject to Separate Payment under OPPS Payment Criteria) under the OPPS for CY 2009. We proposed to create and assign status indicators ''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. We refer readers to section XIII.A.1. of this final rule with comment period for a complete discussion of status indicators and our status indicator changes for CY 2009.

While most conditionally packaged HCPCS codes are assigned to only one of the conditionally packaged categories described above, in the CY 2009 OPPS/ASC proposed rule (73 FR 41453), we proposed to assign one particular HCPCS code to two conditionally packaged categories for CY 2009. Specifically, we proposed to treat CPT code 75635 (Computed tomographic angiography, abdominal aorta and bilateral iliofemoral lower extremity runoff, with contrast material(s), including noncontrast images, if performed, and image postprocessing) as both a ''T-packaged code'' and a component of composite APC 8006 (CT and CTA with Contrast Composite). We proposed to assign this code status indicator ''Q2'' in Addendum B and ''Q3'' in Addendum M, to signify its dual treatment. For CY 2009, we proposed to first assess whether CPT code 75635 would be packaged or separately payable, based on its status as a ''T-packaged code.'' If the service reported with CPT code 75635 would be separately payable due to the absence of another procedure on the claim with status indicator ''T'' for the same date of service, the code would then be assessed in the context of any other relevant imaging services reported on the claim for the same date of service to determine whether payment for CPT code 75635 under composite APC 8006 would be appropriate. If the criteria for payment of the code under composite APC 8006 are not met, then CPT code 75635 would be separately paid based on APC 0662 (CT Angiography) and its corresponding payment rate displayed in Addendum B to this final rule with comment period.

We received many public comments related to the CY 2009 proposals for payment of packaged services that are not drugs. We have responded to public comments on the packaging of payment for drugs, including contrast media and diagnostic radiopharmaceuticals, in section V.B.2.c. of this final rule with comment period.

Comment: Several commenters were pleased that CMS did not propose to extend packaging to additional categories of services for CY 2009. These commenters believed that it was appropriate for CMS to study the effects of newly packaging many services for CY 2008 before choosing to package additional services. One commenter asked that we reconsider all packaging in general because of the adverse financial impact it has on some hospitals.

Many commenters recommended that CMS define principles and/or thresholds to determine whether a HCPCS code should be packaged, consistent with the August 2008 APC Panel recommendation that CMS establish a threshold (for example, a proportion of cases in which the service is provided ancillary and dependent to another service, rate of change in utilization over time, and market penetration) when packaging will be considered. While the APC Panel recommendation was discussed in the context of packaging intravascular ultrasound, intracardiac echocardiography, and fractional flow reserve, those general comments related to a threshold are summarized here.

One commenter suggested the following packaging principles: packaging should be reserved for higher-volume, lower-cost, minor and ancillary services that are frequently performed with an independent service; low volume procedures performed only occasionally in conjunction with the independent service should not be packaged; device-dependent procedures or procedures utilizing both single-use devices and capital equipment designed exclusively for use with that unique service should not be packaged; add-on codes that are infrequently performed among all cases of the independent services they accompany should not be packaged; and exceptions to the packaging policy should be permitted when packaging could unreasonably impede access to valuable technologies. Many commenters suggested that resource costs should be considered when determining whether to package services, in accordance with MedPAC's comment, which stated that packaging should be reserved for ''ancillaries that are frequently provided or inexpensive in relation to the associated independent service.'' Another commenter recommended that CMS should only package items that have substitutes; that CMS should take cost and volume into consideration when determining whether to package a service; and that CMS should package the charges for packaged services in a logical and more deliberate manner, ensuring that packaged costs representing dependent services are allocated only to corresponding independent services. One commenter suggested that CMS should only package payment for a dependent service if the payment rate for the independent service increases appropriately. Many commenters recommended that CMS consider a simple cost threshold, similar to the $60 per day drug packaging threshold that CMS proposed would determine whether payment for most drugs would be packaged or separately paid in CY 2009.

Response: We agree with the commenters that we should examine claims data from CY 2008 that reflect the first year of a significant change in packaging under the OPPS and note that we did not propose to package additional large categories of services for CY 2009 because we wanted a chance to study the effects of packaging payment. We will have CY 2008 claims available for the CY 2010 rulemaking cycle and will determine at that time whether it would be appropriate to propose to package additional categories of services. As noted below in section II.A.4.b.(1) of this final rule with comment period, we plan to review CY

2008 claims data with the APC Panel to assess any changes in utilization patterns of packaged services as previously recommended by the APC Panel.

While we are not adopting additional packaging principles or a nondrug packaging threshold for CY 2009, we understand the concerns of the commenters and are committed to considering this issue further in the future, balancing the concerns of the commenters with our goal of continuing to encourage efficient use of hospital resources. The criteria that the commenters provided are focused almost exclusively on preventing packaging, rather than on determining when packaging would be appropriate. We believe that packaging is appropriate when the nature of a service is such that it is supportive and ancillary to another service, whether or not the dependent service is always furnished with the independent service and regardless of the cost of the supportive ancillary service. For example, we do not want to create financial incentives to use one form of guidance instead of another, or to use guidance all the time, even if a procedure could be performed safely without guidance. In addition, it is not clear whether one set of packaging principles or one threshold could apply to the wide variety of services paid under the OPPS. Moreover, we are fully committed to continuing to advance value-based purchasing by Medicare in the hospital outpatient setting, to further the focus on value of care rather than volume, and we believe that packaging payment into larger payment bundles under the OPPS is an appropriate component of our strategy.

In general, we believe that packaging should reflect the reality of how services are furnished and reported on claims by hospitals. We believe that nonspecific packaging (as opposed to selected code packaging) based on combinations of services observed on hospital claims is appropriate because of the myriad combinations of services that can be appropriately provided together. As explained in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66617), we have used this approach to ratesetting throughout the history of the OPPS, and note that payment for APC groups currently reflects significant nonspecific packaging in many cases. We do not agree with the commenters that we should only package services that are low cost ancillary and supportive services that appear frequently with an independent service. To adopt that policy would essentially negate the concept of averaging that is an underlying premise of a prospective payment system because we would package only services that would increase the payment for the independent service, and hospitals would not have a particular incentive to provide care more efficiently.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to package payment for five categories of ancillary and supportive services for CY 2009, specifically guidance services, image processing services, intraoperative services, imaging supervision and interpretation services, and observation services, that are provided in association with independent, separately paid services, without a specific threshold for the cost or utilization of those supportive services. The final CY 2009 payment policies for contrast media and diagnostic radiopharmaceuticals are discussed in section V.B.2.b. of this final rule with comment period.

b. Service-Specific Packaging Issues

(1) Packaged Services Addressed by the APC Panel Recommendations

The Packaging Subcommittee of the APC Panel was established to review all packaged HCPCS codes. 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 II.A.4.a. of this final rule with comment period regarding our packaging approach for CY 2008, we established packaging criteria that apply to seven categories of codes whose payments are packaged. Four of the APC Panel's packaging recommendations from its March 2008 meeting reference codes are included in the seven categories of services that we packaged for CY 2008. For these four recommendations, we specifically applied the packaging considerations that apply to those seven categories of codes in determining whether a code should be proposed as packaged or separately payable for CY 2009. Specifically, we determined whether a service is a dependent service falling into one of the seven specified categories that is always or almost always provided integral to an independent service. For those two APC Panel recommendations that do not fit into any of the seven categories of services that were part of the CY 2008 packaging approach, we applied the packaging criteria noted above in this section that were historically used under the OPPS. Moreover, we took into consideration our interest in possibly expanding the size of payment groups for component services to provide encounter-based or episode-of-care-based payment in the future in order to encourage hospital efficiency and provide hospitals with maximal flexibility to manage their resources.

The Packaging Subcommittee reviewed the packaging status of numerous HCPCS codes and reported its findings to the APC Panel at its March 2008 meeting. The APC Panel accepted the report of the Packaging Subcommittee, heard several presentations on certain packaged services, discussed the deliberations of the Packaging Subcommittee, and recommended that—

1. CMS provide additional data to support packaging radiation oncology guidance services for review by the Data Subcommittee at the next APC Panel meeting. (Recommendation 1)

2. CPT code 36592 (Collection of blood specimen using established central or peripheral catheter, venous, not otherwise specified) be treated as an ''STVX-packaged code'' for CY 2009 and assigned to the same APC as CPT code 36591 (Collection of blood specimen from a completely implantable venous access device) until adequate data are collected that would enable CMS to determine its own payment rate. (Recommendation 2)

3. HCPCS code A4306 (Disposable drug delivery system, flow rate of less than 50 mL per hour) remain packaged for CY 2009. (Recommendation 3)

4. CPT code 74305 (Cholangiography and/or pancreatography; through existing catheter, radiological supervision and interpretation) be treated as a ''T-packaged code'' for CY 2009 and that CMS consider assigning this code to APC 0263 (Level I Miscellaneous Radiology Procedures). (Recommendation 4)

5. CMS reinstate separate payment for the following intravascular ultrasound and intracardiac echocardiography codes: CPT codes 37250 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel); 37251 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel); 92978 (Intravascular ultrasound (coronary vessel or graft) during diagnostic evaluation and/or therapeutic intervention including

imaging supervision, interpretation and report; initial vessel); 92979 (Intravascular ultrasound (coronary vessel or graft) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel); and 93662 (Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation). (Recommendation 5)

6. CMS continue to package diagnostic radiopharmaceuticals for CY 2009. (Recommendation 6)

7. The Packaging Subcommittee continue its work. (Recommendation 7)

In addition, the Packaging Subcommittee reported its findings to the APC Panel at its August 2008 meeting. The APC Panel accepted the report of the Packaging Subcommittee, heard presentations on several packaged services, discussed the deliberations of the Packaging Subcommittee and recommended that—

8. CMS pay separately for the following IVUS, ICE, and FFR CPT codes: 37250 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel); 37251 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel); 92978 (Intravascular ultrasound (coronary vessel or graft) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel); 92979 (Intravascular ultrasound (coronary vessel or graft) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel); 93662 (Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation); 93571 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, initial vessel); and 93572 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, each additional vessel).

The APC Panel further recommended that CMS establish a threshold (for example, a proportion of cases in which the service is provided ancillary and dependent to another service, rate of change in utilization over time, and market penetration) when packaging will be considered. The APC Panel also recommended that CMS reconsider packaging these codes after 2 years of claims data are available from their period of payment as a separate service. (Recommendation 8)

9. CMS pay separately for radiation therapy guidance for 2 years and then reevaluate packaging on the basis of claims data. The APC Panel further recommended that CMS evaluate possible models for threshold levels for packaging radiation therapy guidance and other new technologies. (Recommendation 9)

10. The Packaging Subcommittee continue its work. (Recommendation 10)

We address each of these recommendations in turn in the discussion that follows.

Recommendation 1 and Recommendation 9

We indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41454) that we are adopting this APC Panel recommendation for CY 2009 and as requested, we provided data related to radiation oncology guidance services to the Data Subcommittee at the APC Panel's August 2008 meeting. The APC Panel at its August 2008 meeting recommended that CMS pay separately for image-guidance for radiation therapy (IGRT) for 2 years and then reevaluate packaging on the basis of claims data. The APC Panel further recommended that CMS evaluate possible models for threshold levels for packaging radiation therapy guidance and other new technologies.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41454), we proposed to maintain the packaged status of radiation oncology guidance services for CY 2009. Specifically, we proposed to continue to package payment for the services reported with CPT codes 76950 (Ultrasonic guidance for placement of radiation therapy fields); 76965 (Ultrasonic guidance for interstitial radioelement application); 77014 (Computed tomography guidance for placement of radiation therapy fields); 77417 (Therapeutic radiation port film(s)); and 77421 (Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy). These services are ancillary and dependent in relation to the radiation therapy services with which they are most commonly furnished. Consistent with the principles of a prospective payment system, in some cases payment in an individual case exceeds the average cost, and in other cases payment is less than the average cost, but on balance, payment should approximate the relative cost of the average case. While we noted that we are aware that some of the radiation oncology guidance codes describe relatively new technologies, we do not believe that beneficiary access to care would be harmed by packaging payment for radiation oncology guidance services. We believe that packaging creates incentives for hospitals and their physician partners to work together to establish appropriate protocols that will eliminate unnecessary services where they exist and institutionalize approaches to providing necessary services more efficiently. Therefore, we saw no basis for treating radiation oncology services differently from other guidance services that are ancillary and dependent to the procedures they facilitate.

Comment: Several commenters asked that CMS pay separately for IGRT guidance that represent new guidance technologies for at least the first 2 to 3 years of the use of the new service so that diffusion of the new service is not compromised by the absence of separate payment for it and that CMS evaluate possible models for threshold levels for packaging radiation therapy guidance and other new technologies. The commenters objected to the continued packaging of these services for CY 2009 on the basis that packaging creates significant financial disincentives to the use of these services which they believed enhance the quality of care. These commenters believed that packaging will delay adoption of new technologies by hospitals and that this will hinder access to improved care for Medicare beneficiaries. They suggested that advances in radiation therapy delivery are associated with higher technical costs and more demanding, time-consuming services that ensure the safe delivery of high quality care. The commenters asked that if CMS continues to package these services, it should closely monitor the impact of packaging imaging guidance on the quality of care furnished to Medicare beneficiaries and to provide transparent and meaningful data associated with the packaging, which would allow stakeholders to determine if payment for imaging guidance technology is reasonable and appropriate. Several commenters raised concern that the packaging policy for new guidance technologies may make it more difficult for new services to be approved for payment under New Technology APCs if CMS considers guidance to be supportive and ancillary, rather than a separately paid complete service.

Response: From the perspective of the Medicare program as a value-based purchaser, we believe that packaged payment causes hospitals to carefully consider whether the purchase of or use of a technology is appropriate in an individual case, while separate payment may create incentives to furnish services regardless of whether they are the most appropriate for an individual patient's particular needs. We also believe that where new technologies are proven to improve the quality of care, their utilization will increase appropriately, whether the payment for them is packaged or not. Moreover, we note that the history of technology development shows that new technologies do not necessarily result in the forecasted improvements over existing technologies. Often a period of some years of broad use is necessary to effectively assess whether the new technology improves, harms, or yields no improvement in patient health and quality of life. Furthermore, we also do not believe that hospitals would fail to provide services to Medicare beneficiaries while furnishing the same services to other patients with the same clinical needs, because to do so would jeopardize the hospital's continued participation in Medicare. Specifically, under § 489.53, CMS may terminate the Medicare participation of a hospital that places restrictions on the persons it will accept for treatment and either fails to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking treatment. We have already addressed the issue of establishing a threshold for a determination of whether to package a service in our response to general comments on packaging above in this section.

We understand the concerns of the commenters who noted that it may be harder for new guidance services to become eligible for assignment to a New Technology APC. As we stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66621), we assess applications for New Technology APC placement on a case-by-case basis. The commenters are correct that, to qualify for New Technology APC placement, the service must be a complete service, by which we mean a comprehensive service that stands alone as a meaningful diagnostic or therapeutic service. To the extent that a service for which New Technology APC status is being requested is ancillary and supportive of another service, for example, a new intraoperative service or a new guidance service, we might not consider it to be a complete service because its value is as part of an independent service. However, if the entire, complete service, including the guidance component of the service, for example, is ''truly new,'' as we explained that term at length in the November 30, 2001 final rule (66 FR 59898) which sets forth the criteria for eligibility for assignment of services to New Technology APCs, we would consider the new complete procedure for New Technology APC assignment. As stated in that November 30, 2001 final rule, by way of examples provided, ''The use of a new expensive instrument for tissue debridement or a new, expensive wound dressing does not in and of itself warrant creation of a new HCPCS code to describe the instrument or dressing; rather, the existing wound repair code appropriately describes the service that is being furnished * * *'' (66 FR 59898). This example may be applicable for some new guidance technologies as well.

The OPPS pays for certain new technology services through New Technology APC assignment. One of the criteria requires the new technology service to be a complete service. If we were to pay separately for new guidance technologies, in many cases hospitals would receive duplicate payment when providing a comprehensive, independent service, through payment for the independent service that already has guidance costs packaged into its payment rate and the new guidance service that was provided separate payment. In addition, if we were to pay separately for new guidance technologies, we would create a payment incentive to use one form of guidance instead of another. Therefore, by packaging payment for all forms of guidance, we specifically encourage hospitals to utilize the most cost effective and clinically advantageous method of guidance that is appropriate in each situation by providing hospitals with the maximum flexibility associated with a single payment for the independent procedure.

We further note that the OPPS pays separately for new items through the pass-through payment provisions for drugs, biologicals, and device categories. The criteria for a drug, biological, or device category to be eligible for pass-through payment status are different than the criteria for a new service to be eligible for assignment to a New Technology APC. These criteria and processes are listed on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/04_pass through_payment.asp#TopOfPage*. One requirement for separate pass-through payment for implantable devices, which are all packaged if they do not have pass-through status, is that the applicant for the pass-through device category must demonstrate that use of the device results in substantial clinical improvement in the diagnosis or treatment of a Medicare beneficiary in comparison with currently available tests or treatments. Thus, in some cases we may not pay separately under the pass-through provisions for some new or modified implantable devices because the evidence to support substantial clinical improvement may not be available early in the device's use. Instead, like new or modified guidance or other nonimplantable technologies that are not complete services, the cost of the new or modified device is incorporated into the OPPS payment rates for the associated procedures as the device is adopted into medical practice and its utilization increases, and OPPS payment rates come to reflect hospital charges for the new or modified device. In many cases, the new or modified device may be replacing a predecessor device whose cost is already reflected in the OPPS payments for the associated procedures. As stated in the ''Innovator's Guide to Navigating CMS,'' posted on the CMS Web site at *http://www.cms.hhs.gov/CouncilonTechInnov/Downloads/InnovatorsGuide8_25_08.pdf* , CMS pays for many new technologies under various payment systems, including the OPPS, without requiring an explicit payment decision by CMS.

Comment: Several commenters objected to the packaging of IGRT guidance because they believed that there is a fundamental difference between diagnostic imaging support services, which they suggested may be more easily correlated with specific independent procedures, and therapeutic imaging guidance services, which they stated are used to enhance the precise delivery of many different radiation therapy procedures. They believed that CMS should not package IGRT guidance services because they cannot be identified with a single specific therapeutic service.

Response: We disagree that IGRT guidance services are so fundamentally different in function from other imaging support services that the packaging policy is inappropriately applied to them. In both cases, the dependent services are being furnished to support a service that could be performed independently of the image guidance service, whether on the same day or soon thereafter. Moreover, we do not believe that diagnostic imaging support services are necessarily more

specifically linked to any one specific diagnostic service than are the IGRT guidance services, nor do we believe that this is relevant in considering whether the service can be appropriately packaged. Therefore, we do not believe that there is a fundamental distinction between IGRT and other guidance services that causes packaging to be inappropriate for the IGRT subset of these services.

Comment: A number of commenters indicated that packaging for radiation therapy guidance was particularly inappropriate because the OPPS payments for the separately paid independent services were simultaneously reduced. The commenters explained that their review of the CY 2007 claims data on which the proposed CY 2009 OPPS payment rates are based revealed that fewer than 10 percent of the billed lines for these radiation therapy guidance codes were used in setting the proposed CY 2009 OPPS payment rates. They also stated that more than one-third of the billed lines for IGRT guidance services were being packaged into single claims for services that are totally unrelated to radiation oncology. These commenters believed that this may occur in part as a result of the inclusion of radiation oncology services on the bypass list, but that nevertheless, it is inequitable and inappropriate to impose a packaging policy for IGRT guidance that does not package the costs of these services into payment for the associated radiation oncology services. Moreover, the commenters feared that the problem of packaged costs that were lost in ratesetting would be exacerbated in the future because hospitals would cease to report the IGRT services they provide because no separate payment would be made. Without reporting of the HCPCS codes, the commenter asserted, the costs of IGRT guidance would not be available to be packaged in ratesetting for radiation oncology services.

Response: In response to the commenters' concerns with the data, we examined our claims data and determined that the inclusion on the bypass list of certain radiation oncology CPT codes, specifically 77261 (Therapeutic radiology treatment planning, simple) through and including 77799 (Unlisted procedure clinical brachytherapy), may be responsible for the loss or misassignment of packaging for the IGRT guidance codes. A number of these codes had been historically included on the bypass list based on clinical evaluation and past public comments although they failed to meet the empirical criteria for inclusion on the bypass list. Therefore, for CY 2009, we are removing those radiation oncology codes from the bypass list that do not meet the empirical criteria. We discuss these changes to the bypass list in section II.A.1.b. of this final rule with public comment period.

As a result of these changes to the bypass list, the median costs for APCs 0412 (IMRT Treatment Delivery) and 0304 (Level I Therapeutic Treatment Preparation) increased by more than 9 percent compared to the median costs used to calculate the proposed CY 2009 OPPS payment rates. Furthermore, Table 10 below displays the historical and final CY 2009 payment rates for the common combination of intensity modulated radiation therapy (IMRT) described by CPT code 77418 (Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session) and IGRT guidance described by CPT code 77421 (Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy). Packaging payment for IGRT guidance services notably increases the payment rate for IMRT. Specifically, the packaging of IGRT guidance services results in an approximately $50 increase to the CY 2009 median cost for APC 0412, the APC that includes IMRT, as compared to the APC's median cost without packaged IGRT guidance.

TABLE 10—HISTORICAL PAYMENT FOR RADIATION TREATMENT AND IGRT GUIDANCE SERVICES

	CY 2006	CY 2007	CY 2008	CY 2009
Payment for Radiation Treatment—IMRT (CPT code 77418)	$319	$336	$348	$411
Payment for IGRT Guidance (CPT Code 77421)	75	67	N/A *	N/A *
Total Payment for IMRT & IGRT Guidance	394	403	348	411

* Packaged payment.

On the other hand, as a result of these changes to the bypass list we were unable to use nearly a million claims that would otherwise have been used, in whole or in part, to calculate median costs for the radiation oncology APCs and other APCs. Moreover, the median costs for some of the radiation oncology APCs declined, most notably the brachytherapy source application APCs, 0651 (Complex interstitial radiation source application); 0312 (Radioelement applications); and 8001 (Low dose rate prostate brachytherapy). As we discuss in section II.A.1.b. of this final rule with comment period, we are exploring whether we can identify specific radiation oncology codes that could safely be added back into the bypass list that would enable us to use more claims data for these APCs without the effect of loss or misassignment of packaging. We welcome comments on the specific radiation oncology CPT codes that would achieve this goal. However, for CY 2009, we will base payments on the median costs calculated from the smaller number of single bills for the brachytherapy source application APCs that result from the removal of radiation oncology codes that do not meet the empirical bypass list criteria from the bypass list because we want to ensure that all costs of IGRT guidance services are packaged appropriately for CY 2009 ratesetting.

We strongly encourage hospitals to report a charge for each packaged service they furnish, either by billing the packaged HCPCS code and a charge for that service if separate reporting is consistent with CPT and CMS instructions, by increasing the charge for the separately paid associated service to include the charge for the packaged service, or by reporting the charge for the packaged service with an appropriate revenue code but without a HCPCS code. Any of these means of charging for the packaged service will result in the costs of the packaged service being incorporated into the cost we estimate for the separately paid service. We believe that hospitals will continue to charge for these packaged services, individually or as part of the charge for the independent service, because hospitals must charge all payers the same amount for services they furnish to patients and because some other payers pay a percentage of charges. To fail to charge for the packaged service would result in immediately reduced payment from sources other than Medicare, and over

time, could also lead to a reduction in payment under the OPPS.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to package payment for all IGRT guidance services into payment for the separately paid independent services to which they are ancillary and supportive. We will base all final CY 2009 payments on claims data derived with the use of a bypass list that has been revised to remove the radiation oncology services that do not meet the empirical criteria. We are not adopting the APC Panel recommendation to pay separately for radiation therapy guidance for CY 2009. We will consider the issue of a threshold for packaging, as recommended by the APC Panel, in the future, balancing the concerns over access to high quality medical care with the goal of continuing to encourage efficient use of hospital resources.

Recommendation 2

We indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41454) that we are adopting this APC Panel recommendation. For CY 2009, we proposed to treat CPT code 36592 (Collection of blood specimen using established central or peripheral catheter, venous, not otherwise specified) as an ''STVX-packaged code'' and assign it to APC 0624 (Phlebotomy and Minor Vascular Access Device Procedures), the same APC to which we proposed to assign CPT code 36591 (Collection of blood specimen from a completely implantable venous access device). CPT code 36591 became effective January 1, 2008, and was assigned interim status indicator ''Q,'' with treatment as an ''STVX-packaged code'' and assignment to APC 0624. CPT code 36591 was a direct replacement for CPT code 36540, which was deleted effective January 1, 2008, but was an ''STVX-packaged code'' with assignment to APC 0624 for CY 2007. CPT code 36592 became effective January 1, 2008, and was assigned interim status indicator ''N'' in the CY 2008 OPPS/ASC final rule with comment period.

In summary, for CY 2009, we proposed to change the packaged status of CPT code 36592 from unconditionally packaged to conditionally packaged, as an ''STVX-packaged code,'' which was parallel to the proposed treatment of CPT code 36591. This service would be paid separately when it is provided in an encounter without a service assigned status indicator ''S,'' ''T,'' ''V,'' or ''X.'' In all other circumstances, its payment would be packaged. As noted above in section II.A.4.a. of this final rule with comment period, for CY 2009, we proposed to further refine our identification of the different types of conditionally packaged HCPCS codes that were previously all assigned status indicator ''Q'' (Packaged Services Subject to Separate Payment under OPPS Payment Criteria) under the OPPS. Therefore, we proposed to assign status indicator ''Q1'' to CPT code 36592 for CY 2009, which indicates that it is an ''STVX-packaged code.'' We refer readers to section XIII.A.1. of this final rule with comment period for a complete discussion of status indicators and our status indicator changes for CY 2009.

Comment: One commenter requested that CMS change the status of CPT code 36592 from unconditionally to conditionally packaged, treating it like CPT code 36591. The commenter stated that the resource costs associated with drawing blood from an established central or peripheral catheter were almost identical to the resources associated with drawing blood from an implanted venous access device. Several other commenters noted that they supported the proposal to assign status indicator ''Q1'' to CPT code 36592 for CY 2009.

Response: We appreciate the commenters' support. We agree that the resource costs associated with CPT code 36592 may be similar to the resource costs associated with CPT code 36591. When CY 2008 cost data for CPT code 36592 are available for the CY 2010 OPPS annual update, we will reevaluate whether assignment to APC 0624 continues to be appropriate.

Comment: One commenter asked whether hospitals must follow the parenthetical CPT guidance listed immediately following the code descriptor that states that CPT code 36592 may not be reported with any other service. The commenter asked why CMS proposed to change the status of this code from unconditionally packaged to conditionally packaged if the code descriptor states that this code would never be provided with another service. The commenter contended that there does not appear to be any reason to treat this code as conditionally packaged.

Response: Hospitals must follow the coding guidance provided by CPT. We are not recommending that hospitals report CPT code 36592 every time it is performed, even if provided at the same time as another procedure or visit. Our proposed payment policy would ensure that, if CPT code 36592 was reported with other services paid under the OPPS, hospitals would not receive separate payment. Therefore, our payment proposal to conditionally package CPT code 36592 is consistent with the reporting guidance provided by CPT.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, and adopting the APC Panel's recommendation to conditionally package CPT code 36592 as an ''STVX-packaged code'' for CY 2009. This CPT code will be paid separately through APC 0624 when criteria for packaged payment are not met. As noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41454), we expect hospitals to follow the CPT guidance related to CPT codes 36591 and 36592 regarding when these services should be appropriately reported.

Recommendation 3

In the CY 2009 OPPS/ASC proposed rule (73 FR 41455), we indicated that we are adopting this APC Panel recommendation. For CY 2009, we proposed to maintain the packaged status of HCPCS code A4306 (Disposable drug delivery system, flow rate of less than 50 mL per hour).

HCPCS code A4306 describes a disposable drug delivery system with a flow rate of less than 50 mL per hour. Beginning in CY 2007, HCPCS code A4306 is payable under the OPPS with status indicator ''N,'' indicating that its payment is unconditionally packaged. We packaged this code because it is considered a supply, and under the OPPS it is standard to package payment for all supplies, including implantable and nonimplantable supplies, into payment for the procedures in which the supplies are used. We first discussed this code with the APC Panel in March 2007. During the APC Panel's March 2007 meeting, a manufacturer noted in a presentation that a particular disposable drug delivery system reported with HCPCS code A4306 is specifically used to treat postoperative pain. The manufacturer requested that this code be moved to its own APC for CY 2008 in order for the service to receive separate payment. During its September 2007 meeting, the APC Panel recommended that CPT code A4306 remain packaged for CY 2008 and asked CMS to present additional data regarding this code to the APC Panel when available.

During the APC Panel's March 2008 meeting, we provided to the Packaging Subcommittee additional cost data related to this code. Our CY 2007 proposed rule claims data indicate that HCPCS code A4306 was billed on OPPS

claims approximately 2,400 times, yielding a line-item median cost of approximately $4. The individual costs for this supply range from $4 per unit to $2,056 per unit. The Packaging Subcommittee suggested that this code may not always be correctly reported by hospitals as the data also show that this code was frequently billed together with computed tomography (CT) scans of various regions of the body, without surgical procedures on the same date of service. The APC Panel speculated that this code may be currently reported when other types of drug delivery devices are utilized for nonsurgical procedures or for purposes other than the treatment of postoperative pain. It was also noted that hospitals may actually be appropriately reporting HCPCS code A4306, which may be used to describe supplies used for purposes other than postoperative pain relief.

In summary, because HCPCS code A4306 represents a supply and payment of supplies is packaged under the OPPS according to longstanding policy, we proposed to maintain the unconditionally packaged status of HCPCS code A4306 for CY 2009.

Comment: One commenter believed that hospitals are misreporting CPT code A4306, leading to inaccurate cost estimates and payment rates. The commenter asked CMS to clarify that this supply code is for single use infusion pump devices used for chemotherapy, not syringes for chemotherapy or pain drugs. The commenter also asked CMS to clarify that hospitals should not report HCPCS code A4306 for syringes prefilled with sodium chloride or other material.

Response: In general, it is not our practice to provide specific coding guidance regarding permanent Level II HCPCS codes, such as HCPCS code A4306. As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66669), we encourage interested parties to submit any questions or requests for clarification of the HCPCS codes to the AHA coding clinic.

After consideration of the public comment received, we are finalizing our CY 2009 proposal, without modification, and adopting the APC Panel recommendation to maintain the unconditionally packaged status of HCPCS code A4306.

Recommendation 4

In the CY 2009 OPPS/ASC proposed rule (73 FR 41455), we indicated that we are adopting this APC Panel recommendation. For CY 2009, we proposed to treat CPT code 74305 (Cholangiography and/or pancreatography; through existing catheter, radiological supervision and interpretation) as a ''T-packaged code'' and assign it to APC 0263 (Level I Miscellaneous Radiology Procedures).

Effective January 1, 2008, CPT code 74305 is unconditionally packaged and falls into the imaging supervision and interpretation category of codes that we created as part of the CY 2008 packaging approach. Several members of the public recently noted that CPT code 74305 may sometimes be provided in a single hospital encounter with CPT code 47505 (Injection procedure for cholangiography through an existing catheter (e.g., percutaneous transepatic or T-tube)), which is unconditionally packaged itself, when these are the only two services reported on a claim. In the case where only these two services were performed, the hospital would receive no separate payment. Our claims data indicate that CPT code 74305 is infrequently provided without any other separately payable services on the same date of service.

Therefore, for CY 2009, we proposed to change the packaged status of CPT code 74305 from unconditionally packaged to conditionally packaged, as a ''T-packaged code,'' which is parallel to the treatment of many other conditionally packaged imaging supervision and interpretation codes. Hospitals would receive separate payment for this service when it appears on a claim without a surgical procedure. The payment for this service would be packaged into payment for a status indicator ''T'' surgical procedure when it appears on the same date as a surgical procedure. Hospitals that furnish this imaging supervision and interpretation service on the same date as an independent surgical procedure assigned status indicator ''T'' must bill both services on the same claim.

As noted above in section II.A.4.a. of this final rule with comment period, for CY 2009, we proposed to further refine our identification of the different types of conditionally packaged HCPCS codes that were previously all assigned status indicator ''Q'' (Packaged Services Subject to Separate Payment under OPPS Payment Criteria) under the OPPS. Therefore, we proposed to assign status indicator ''Q2'' to CPT code 74305 for CY 2009, which indicates that it is a ''T-packaged code.'' We refer readers to section XIII.A.1. of this final rule with comment period for a complete discussion of status indicators and our status indicator changes for CY 2009.

In summary, for CY 2009, we proposed to change the status indicator for CPT code 74305 from ''N'' to ''Q2,'' with assignment to APC 0263 (Level I Miscellaneous Radiology Procedures) when it would be paid separately.

Comment: Several commenters supported the CY 2009 proposal to change the status indicator for CPT code 74305 from ''N'' to ''Q2,'' with assignment to APC 0263 when it would be paid separately. One commenter requested that CMS change the status indicator of this code retroactive to January 1, 2008, when this code became unconditionally packaged.

Response: We are pleased that commenters supported this proposal. We established the final unconditionally packaged status of CPT code 74305 for CY 2008 through the CY 2008 OPPS/ASC rulemaking cycle. We note that we proposed to unconditionally package CPT code 74305 in the CY 2008 OPPS/ASC proposed rule and we did not receive any public comments opposing this proposal. Therefore, we finalized our policy to unconditionally package CPT code 74305 for CY 2008.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, and adopting the APC Panel recommendation to conditionally package CPT code 74305 as a ''T-packaged code'' for CY 2009, with payment through APC 0263 when the criteria for packaged payment are not met.

Recommendation 5 and Recommendation 8

For CY 2009, we proposed to maintain the packaged status of CPT codes 37250 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; initial vessel); 37251 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel); 92978 (Intravascular ultrasound (coronary vessel or graft) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel); 92979 (Intravascular ultrasound (coronary vessel or graft) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel); and 93662 (Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation). Our CY 2009 proposal indicated that we are not adopting the APC Panel's recommendation to pay separately for these intraoperative intravascular ultrasound (IVUS) and

intracardiac echocardiography (ICE) services for CY 2009.

These services were newly packaged for CY 2008 because they were members of the intraoperative category of services that were included in the CY 2008 packaging approach. The intraoperative category includes those codes that are reported for supportive dependent diagnostic testing or other minor procedures performed during surgical or other independent procedures. Because these intraoperative IVUS and ICE services support the performance of an independent procedure and are provided in the same operative session as the independent procedure, we packaged their payment into the OPPS payment for the independent procedure performed in CY 2008. We believe these IVUS and ICE services are always integral to and dependent upon the independent services that they support and, therefore, we believe their payment would be appropriately packaged into the independent procedure.

A presenter at the March 2008 APC Panel meeting requested separate payment for these services, noting that they are high cost and provided with relatively low frequency compared to the services they typically accompany. We continue to believe that these services are ancillary and dependent in relation to the independent cardiac and vascular procedures with which they are most commonly furnished. We note that resource cost was not a factor we considered when deciding to package intraoperative services. Packaging payment for items and services that are directly related to performing a procedure, even when those packaged items and services have variable resource costs or different frequencies of use in relationship to one another or to the independent services into which their payment is packaged, has been a principle of the OPPS since the inception of that payment system. For example, once an implantable device is no longer eligible for device pass-through payment, our standard policy is to package the payment for the device into the payment for the procedures with which the device was reported. These former pass-through devices may be high or low cost in relationship to the other costs of the associated surgical procedures, or the devices may be implanted in a large or small proportion of those surgical procedures, but the device payment is nevertheless packaged. We do not believe that the fact that a procedure may be performed with assorted technologies of varying resource costs is a sufficient reason to pay separately for a particular technology that is clearly ancillary and dependent in relationship to independent associated procedures. We acknowledged in the CY 2009 OPPS/ASC proposed rule that the costs associated with packaged services may contribute more or less to the median cost of the independent service, depending on how often the dependent service is billed with the independent service (73 FR 41456). Consistent with the principles of a prospective payment system, in some cases payment in an individual case exceeds the average cost, and in other cases payment is less than the average cost, but on balance, payment should approximate the relative cost of the average case. While we understand that these services represent technologies that are not commonly used in most hospitals, we do not believe that beneficiary access to care would be harmed by packaging payment for IVUS and ICE services. We noted that IVUS and ICE services are existing, established technologies and that hospitals have provided some of these services in the HOPD since the implementation of the OPPS in CY 2000. We believe that packaging will create incentives for hospitals and their physician partners to work together to establish appropriate protocols that will eliminate unnecessary services where they exist and institutionalize approaches to providing necessary services more efficiently. Therefore, in the CY 2009 OPPS/ASC proposed rule (73 FR 41456), we indicated that we saw no basis for treating IVUS and ICE services differently from other intraoperative services that are ancillary and dependent to the procedure they facilitate.

In summary, we proposed to maintain the unconditionally packaged status of CPT codes 37250, 37251, 92978, 92979, and 93662 for CY 2009.

As noted above in this section, during its August 2008 meeting, the APC Panel discussed these services and recommended that CMS pay separately for CPT codes 37250, 37251, 92978, 92979, 93662, as well as 93571 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, initial vessel); and 93572 (Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, each additional vessel).

In addition, the APC Panel further recommended that CMS establish a threshold (for example, a proportion of cases in which the service is provided ancillary and dependent to another service, rate of change in utilization over time, and market penetration) when packaging will be considered. The APC Panel also recommended that CMS reconsider packaging these codes after it has 2 years of claims data available from their period of payment as a separate service.

Comment: Many commenters were disappointed that CMS did not propose to provide separate payment for CPT codes 37250, 37251, 92978, 92979, and 93662 for CY 2009, in accordance with the March 2008 APC Panel recommendation, and requested that CMS adopt the APC Panel's August 2008 recommendation to pay separately for these services (and CPT codes 93571 and 93572) for CYs 2009 and 2010. These commenters believed that separate payment for 2 years would allow CMS to accurately capture cost data. Other commenters clarified that services should only be eligible for packaging if they have been separately payable for 2 years, thereby enabling CMS to capture complete cost data. The commenters indicated that payment for the independent procedures provided in conjunction with IVUS are not sufficient to cover the incremental cost of providing IVUS. The commenters also were concerned that packaging these technologies creates a strong disincentive for hospitals to use these important technologies. Other commenters requested that CMS develop a composite APC whose payment criteria would be met when IVUS, ICE, or FFR are provided.

The commenters estimated the IVUS and ICE are utilized in less than 10 percent of Medicare beneficiaries undergoing a diagnostic cardiac catheterization procedure, or other related procedures, which results in their costs having little or no impact on the payment for the independent procedure. Furthermore, many commenters emphasized that limited access to these technologies would result in greater utilization of interventional procedures that could have been avoided had these interventions been used. One commenter disputed describing FFR services as ''ancillary'' and stated that they are ''decisional'' and, therefore, should not be packaged, or should become conditionally packaged. Several commenters were concerned that packaged payment would create a significant financial disincentive to provide these services. The commenters also noted that these procedures should not be described as ''intraoperative'' because they precede the independent procedure, and may even result in

canceling the independent procedure. One commenter acknowledged the reference in the CY 2009 OPPS/ASC proposed rule (73 FR 41555 to 41556) that CMS does not believe that beneficiary access would be harmed, but asked CMS to provide support for this assumption. Another commenter indicated that even with separate payment in the past, only a small number of hospitals purchased this technology. Therefore, the commenter was concerned that with packaged payment, access to this technology would be even more severely limited. Many commenters developed and shared criteria and/or principles that they suggested should dictate whether an item or service is eligible for packaged payment, both for determining the packaged status of IVUS, ICE, and FFR, as well as other services.

Response: We appreciate the many detailed comments related to the packaged status of IVUS, FFR, and ICE services. We acknowledge that the costs associated with packaged services may contribute more or less to the median cost of the independent service, depending on how often the dependent service is billed with the independent service. It is our goal to adhere to the principles inherent in a prospective payment system and to encourage hospitals to utilize resources in a cost-effective manner. In this case, hospitals may choose whether to utilize IVUS, FFR, and ICE services, balancing the needs of the patient with the costs associated with the services.

We note that IVUS, ICE, and FFR services had been separately payable under the OPPS prior to CY 2008, and hospitals were paid separately each time they provided IVUS, ICE, or FFR services. In addition, according to several manufacturers, these technologies are not new and have been widely available for at least the past 5 to 10 years. In fact, every one of the CPT codes describing IVUS and ICE services (CPT codes 37250, 37251, 92978, 92979, and 93662) has been separately payable under the OPPS since CY 2001, or earlier. FFR services (CPT code 93571 and 93572) have been separately payable since CY 2005.

In general, we believe that hospitals adopt technologies when it is clinically advantageous and financially feasible to do so. The fact that these technologies have not been provided by a larger number of hospitals prior to CY 2008 is, therefore, not a function of separate versus packaged Medicare hospital outpatient payment. We do not believe that packaged payment is harming access to these technologies that have been separately paid for many years. Similarly, we do not believe that another 2 years of separate payment is necessary to increase Medicare beneficiaries' access to these services.

We also do not agree that beneficiary access to care will be harmed by packaging payment for these services. We believe that packaging will create incentives for hospitals and their physician partners to work together to establish appropriate protocols that will eliminate unnecessary services where they exist and will institutionalize approaches to providing necessary services more efficiently. Where this review results in the reductions in services that are only marginally beneficial, we believe that this could improve rather than harm the quality of care for beneficiaries because every service furnished in a hospital carries some level of risk to the patient. Similarly, where this review results in the concentration of some services in a reduced number of hospitals in the community, we believe that the quality of care and hospital efficiency may both be enhanced as a result. The medical literature shows that concentration of services in certain hospitals often results in both greater efficiency and higher quality of care for patients.

We continue to believe that IVUS, FFR, and ICE are dependent services that are always provided in association with independent services. Those independent services may be diagnostic and/or therapeutic or interventional. This is different than stating that every angioplasty or other related independent procedure utilizes IVUS, FFR, or ICE. In fact, all of the codes about which we received public comments are listed as add-on codes in the CY 2007 CPT book. While we agree that some of these services may contribute to decisionmaking regarding a potential therapeutic procedure, we still believe that these services are never provided without another independent service that is separately paid under the OPPS also performed on the same day. Therefore, we do not believe it would be appropriate to conditionally package CPT codes 93571 and 93572, or any of the other IVUS or ICE services.

We have responded to public comments related to general packaging criteria, thresholds, and/or principles earlier in this section. After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to unconditionally packaged payment for IVUS, ICE, and FFR services for CY 2009. We are not adopting the APC Panel recommendation to pay separately for these services. We will discuss these services with the APC Panel at its first 2009 meeting, in addition to reviewing CY 2008 claims data with the APC Panel to assess any changes in utilization patterns of the packaged services as previously recommended by the APC Panel.

Recommendation 6

We indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41456) that we are adopting this APC Panel recommendation. For CY 2009, we proposed to maintain the packaged status of diagnostic radiopharmaceuticals. This recommendation is discussed in detail in section V.B.2.b. of this final rule with comment period.

Recommendation 7 and Recommendation 10

In response to the APC Panel's recommendation for the Packaging Subcommittee to remain active until the next APC Panel meeting, we note that the APC Panel Packaging Subcommittee remains active, and additional issues and new data concerning the packaging status of codes will be shared for its consideration as information becomes available. We continue to encourage submission of common clinical scenarios involving currently packaged HCPCS codes to the Packaging Subcommittee for its ongoing review, and we also encourage recommendations of 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.

Comment: Several commenters supported the recommendation that the Packaging Subcommittee continue, noting that they rely on the Subcommittee to thoroughly review data and carefully deliberate regarding the proper packaged status of various services.

Response: We are pleased that commenters support the work of the Packaging Subcommittee. The Packaging Subcommittee will continue to remain active.

(2) IVIG Preadministration-Related Services

In the CY 2009 OPPS/ASC proposed rule (73 FR 41456 and 41457), we proposed to package payment for HCPCS code G0332 (Services for intravenous infusion of immunoglobulin prior to administration (this service is to be billed in conjunction with administration of immunoglobulin)) for CY 2009. Immune

globulin is a complicated biological product that is purified from human plasma obtained from human plasma donors. In past years, there have been issues reported with the supply of intravenous immune globulin (IVIG) due to numerous factors, including decreased manufacturing capacity, increased usage, more sophisticated processing steps, and low demand for byproducts from IVIG fractionation.

Under the OPPS, the current CY 2008 payment methodology for IVIG treatments consists of three components, which include payment for the drug itself (described by a HCPCS J-code), administration of the IVIG product (described by one or more CPT codes), and the preadministration-related services (HCPCS code G0332). The CY 2009 OPPS payment rates for IVIG products are established based on the Part B ASP drug methodology, as discussed further in section V.B.3. of this final rule with comment period. Under the OPPS, payment is made separately for the administration of IVIG and those services are reported using the CPT code for the first hour and, as needed, additional hour CPT infusion codes. The CY 2009 OPPS payments for drug administration services are discussed in section VIII.B. of this final rule with comment period.

As explained in detail in the CY 2006 OPPS, CY 2007 OPPS/ASC, and CY 2008 OPPS/ASC final rules with comment period (70 FR 68648 to 68650, 71 FR 68092 to 68093, and 72 FR 66697 to 66698, respectively), we temporarily paid separately for the IVIG preadministration-related services in CYs 2006, 2007, and 2008 in order to assist in ensuring appropriate access to IVIG during a period of market instability due, in part, to the implementation of the new ASP payment methodology for IVIG drugs. The preadministration-related payment was designed to pay the hospital for the added costs of obtaining the IVIG and scheduling the patient infusion during a period of market uncertainty. Under the CYs 2006 and 2007 OPPS, HCPCS code G0332 was assigned to New Technology APC 1502 (New Technology—Level II ($50–$100)), with a payment rate of $75. For CY 2008, HCPCS code G0332 was reassigned to APC 0430 (Drug Preadministration-Related Services), with a payment rate of approximately $38 set prospectively based on robust CY 2006 claims data for this code. In addition, a separate payment for HCPCS code G0332 has been made under the MPFS during the same time period, CY 2006 to CY 2008.

We specifically indicated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66697 through 66698) that we would consider packaging payment for HCPCS code G0332 in future years and that we intended to reevaluate the appropriateness of separate payment for IVIG preadministration-related services for the CY 2009 OPPS rulemaking cycle, especially as we explore the potential for greater packaging under the OPPS. In the CY 2009 OPPS/ASC proposed rule (73 FR 41457), we noted that the Office of the Inspector General's (OIG's) study on the availability and pricing of IVIG published in a report in April 2007 entitled, ''Intravenous Immune Globulin: Medicare Payment and Availability (OEI–03–05–00404),'' found that for the third quarter of CY 2006, just over half of the IVIG sales to hospitals and physicians were at prices below Medicare payment amounts. Relative to the previous three quarters, this represented a substantial increase in the percentage of sales with prices below Medicare amounts. During the third quarter of CY 2006, 56 percent of IVIG sales to hospitals and over 59 percent of IVIG sales to physicians by the three largest distributors occurred at prices below the Medicare payment amounts. We reviewed national CY 2006 and CY 2007 claims data for IVIG drug utilization, as well as utilization of the preadministration-related services HCPCS code. These data show modest increases in the utilization of IVIG drugs and the preadministration-related services code, which suggest that IVIG pricing and access may be improving.

IVIG preadministration-related services are dependent services that are always provided in conjunction with other separately payable services, such as drug administration services, and thus are well suited for packaging into the payment for the separately payable services that they usually accompany. Therefore, consistent with our OPPS payment policy for the facility resources expended to prepare for the administration of all other drugs and biologicals under the OPPS, we believe that payment for the hospital resources required to locate and obtain the appropriate IVIG products and to schedule patients' infusions should be made through the OPPS payment for the associated drug administration services. Furthermore, the cost data that we gathered for the services described by HCPCS code G0332 since CY 2006, including the line-item median cost for the code of approximately $37 from CY 2007 claims data, indicated that the cost of the services is relatively low. Therefore, because HCPCS code G0332 meets our historical criteria for packaged payment, because we paid separately for these services on a temporary basis only, and because we believe that the reported transient market conditions that led us to adopt the separate payment for IVIG preadministration-related services have improved, we indicated in the CY 2009 OPPS/ASC proposed rule our belief that packaged payment is more appropriate for the CY 2009 OPPS, consistent with our ongoing efforts to expand the size of the OPPS payment bundles (73 FR 41457). Therefore, we proposed to assign status indicator ''N'' to HCPCS code G0332 for CY 2009.

For CY 2009, under the MPFS, a proposal was made to discontinue payment for HCPCS code G0332 for CY 2009 (73 FR 38518).

Comment: Most commenters opposed the elimination of the preadministration-related payment in CY 2009. A few commenters requested that the preadministration services payment become permanent for both the OPPS and the MPFS. Some commenters stated that the market conditions for IVIG are not fundamentally different than they were when CMS initially instituted the preadministration services payment in CY 2006. The commenters requested that CMS continue the separate payment until there is more stability in the IVIG market. Several commenters stated that the information CMS presented in the CY 2009 OPPS/ASC proposed rule did not conclusively prove that the IVIG market was stabilizing. They alleged that significant access problems remain.

In response to the findings of the OIG report, some commenters stated that the lag inherent to the ASP pricing system may have played a role in substantially increasing the percentage of IVIG sales at prices below the Medicare payment amounts in the third quarter of 2006. The preadministration-related services payment was cited as providing some assistance to physicians and hospitals who are experiencing problems obtaining IVIG. Several commenters noted that the OIG report could be interpreted as leaving a large percentage of hospitals and physicians unable to acquire IVIG at prices below Medicare's payment amounts. Many commenters stated that they did not believe the introduction of new brand-specific reporting codes for IVIG would result in a more stable marketplace.

One commenter presented patient surveys conducted in CYs 2006, 2007, and 2008 which described access limitations and shifts in the site of service. These surveys were limited in size and surveyed only patients receiving IVIG for primary immune

deficiency. Another commenter referred to a report on IVIG issued in February 2007 entitled, *Analysis of Supply, Distribution, Demand and Access Issues Associated with Immune Globulin Intravenous,* prepared by the Eastern Research Group under contract (Contract No. HHSP23320045012XI) to the Assistant Secretary of Planning and Evaluation in HHS, and cited this report as an important source of information on IVIG usage and patient access.

Response: The separate payment for IVIG preadministration-related services was designed to pay the hospital for the additional, unusual, and temporary costs associated with obtaining IVIG products and scheduling patient infusions during a temporary period of market instability. This payment was never intended to subsidize the OPPS payment for drugs made under the ASP methodology.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41457), we referred to data from the OIG study that indicated that for the third quarter of 2006, just over half of IVIG sales to hospitals and physicians were at prices below Medicare payment amounts. Relative to the previous three quarters, this represented a substantial increase of the percentage of sales with prices below Medicare amounts. We agree with the commenters that it is likely that the increased ASP payments were the result of previous price increases from past quarters influencing future ASP data. Furthermore, we believe that the new HCPCS codes for IVIG products allow the hospital to report and receive payment for the specific product furnished to the patient.

We stated clearly in the CY 2006 OPPS final rule with comment period (70 FR 68649 through 68650) that the preadministration-related services payment policy was a temporary measure to pay hospitals for the unusual and temporary costs associated with procuring IVIG. We expected that these costs would decline over time as hospitals became more familiar with the nuances of the IVIG market and the availability of the limited primary and secondary suppliers in their areas.

We did not reference the report conducted by the Eastern Research Group (Contract No. HHSP23320045012XI) in the CY 2009 OPPS/ASC proposed rule. As the commenter noted, this report provides important comprehensive background on the IVIG marketplace, such as an analysis of the IVIG supply and distribution, and an analysis of the demand for and utilization of IVIG products, including how they are administered and paid, as well as information from the industry and others on physician and patient problems with access to IVIG. The study is a collection of multisource information and provides an understanding of the IVIG marketplace. One limitation of the study is that it depicts the market only up through the first quarter of CY 2006 and it does not include detailed information on IVIG pricing as was provided in the OIG report. The OIG report also contains data from a later time period because it includes data through the third quarter of CY 2006.

We note, based on the information that follows, that the IVIG market today appears more stable than it was in CY 2006. We have reviewed national CY 2006 and CY 2007 claims data for IVIG drug utilization, as well as the utilization of the preadministration-related services HCPCS code. These data show a modest increase in the utilization of IVIG and the preadministration-related services code in both physicians' offices and HOPDs from CY 2006 to CY 2007, after a period of decreased IVIG utilization in physicians' offices with a shift of IVIG infusions to the HOPD in the previous year, which suggest that IVIG pricing and access may be improving.

There were about 3.1 million units of IVIG administered in physicians' offices in CY 2006, and 7.3 million units in HOPDs. In CY 2007, those numbers rose to estimates of 3.3 million units and 8.1 million units in the physician's office and HOPD settings, respectively. Under the OPPS, the total number of days of IVIG increased modestly from CY 2006 to CY 2007, from 113,000 to 119,000. Aggregate allowed IVIG charges in the physician's office setting for CY 2006 were $82 million, while total payments (including beneficiary coinsurance) under the OPPS were $184 million for the same time period. In CY 2007, aggregate allowed charges in the physician's office setting are estimated at $98 million, while total OPPS payments are estimated at $246 million.

In summary, beginning in CY 2007, IVIG utilization increased modestly in both the physician's office setting and the HOPD, after a prior shift to the hospital and away from the physicians' offices, presumably reflecting increasing availability of IVIG and appropriate payment for the drug in both settings.

According to information on the Plasma Protein Therapeutics Association (PPTA) Web site regarding the supply of IVIG, in the past year, while the supply has spiked at various times throughout the year, the supply has remained above or near the 12-month moving average. While we acknowledge that the supply is only one of several factors that influence the market, we believe that an adequate supply is one significant factor that contributes to better access to IVIG for patients.

Therefore, because HCPCS code G0332 meets our historical criteria for packaged payment under the OPPS, because we paid separately for these services on a temporary basis only for 3 years, and because we believe that the reported transient market conditions that led us to adopt the separate payment for IVIG preadministration-related services have improved, we believe that packaged payment is more appropriate for the CY 2009 OPPS, consistent with our ongoing efforts to expand the size of the OPPS payment bundles.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to package payment for IVIG preadministration-related services described by HCPCS code G0332 for CY 2009. The treatment of payment for preadministration-related services under the MPFS is addressed separately in that CY 2009 final rule with comment period. We will continue to work with IVIG stakeholders to understand their concerns regarding the pricing of IVIG and Medicare beneficiary access to this important therapy.

HCPCS code G0332 will be deleted effective January 1, 2009. Therefore, hospitals should report charges for IVIG preadministration-related services in the same manner as hospitals report preadministration-related services charges for other drugs. Hospitals may include the charge for IVIG preadministration-related services on a claim in the charge for the associated drug administration service, in the charge for the IVIG product infused, on an uncoded revenue code line, or in another appropriate manner.

(3) Other Service-Specific Packaging Issues

Based on our CY 2009 proposal to maintain the unconditionally and conditionally packaged payment for services in the seven categories that we originally packaged for CY 2009 (guidance services, image processing services, intraoperative services, imaging supervision and interpretation services, diagnostic radiopharmaceuticals, contrast media, and observation services), we received a number of public comments on individual services that were not specifically discussed in the CY 2009 OPPS/ASC proposed rule or for which

the APC Panel made no specific recommendations.

Comment: Several commenters were concerned that the proposal to package payment for electrodiagnostic guidance for chemodenervation procedures, specifically, CPT codes 95873 (Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)), and 95874 (Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)). These commenters indicated that chemodenervation involves the injection of chemodenervation agents, such as botulinum toxin, to control the symptoms associated with dystonia and other disorders. According to the commenters, physicians often, but not always, use electromyography or electrical stimulation guidance to guide the needle to the most appropriate location. The commenters were concerned that the proposal to package payment for these guidance services may discourage utilization of this particular form of guidance, even when medically appropriate. One commenter also noted that even if the median cost for the chemodenervation procedures increased, the payment rate would not increase because chemodenervation procedures are only a small proportion of all claims in their proposed APC.

Response: We note that the cost of the chemodenervation guidance services will generally be reflected in the median cost for the independent HCPCS code as a function of the frequency that chemodenervation services are reported with that particular HCPCS code. We recognize that in some cases supportive and ancillary dependent services are furnished at high frequency with independent services, and in other cases, they are furnished with independent services at a low frequency. We believe that packaging should reflect the reality of how services are furnished. While the commenters are correct that the chemodenervation procedures reflect only approximately 3 percent of the services that comprise APC 0204 (Level I Nerve Injections), and approximately 20 percent of the services that comprise APC 0205 (Level II Nerve Injections), we note that they appropriately map to these APCs both clinically and in terms of resource use. We also note that CPT codes 64613 (Chemodenervation of muscle(s); neck muscle(s) (eg, for spasmodic torticollis, spasmodic sysphonia) and 64614 (Chemodenervation of muscle(s); extremity(s) and/or trunk muscle(s) (eg, for dystonia, cerebral palsy, multiple sclerosis) are assigned to APC 0205 for CY 2009, which has a higher payment rate than APC 0204, where they were assigned for CY 2008, based on our annual review of clinical and resource homogeneity.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to package payment for chemodenervation guidance services described by CPT codes 95873 and 95874 for CY 2009.

Comment: One commenter requested separate payment for CPT codes 0174T (Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation (List separately in addition to code for primary procedure)) and 0175T (Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation), and expressed concern that CMS' CY 2009 proposal did not adopt the March 2007 APC Panel recommendation related to these services. Another commenter stated that computer-aided detection services should not be treated as image processing services because they require extensive performance testing by the Food and Drug Administration (FDA), as compared to general image processing services that are not required to meet the same performance standards.

Response: During its March 2007 meeting, the APC Panel recommended conditional packaging for CPT code 0175T, but did not recommend a change to the unconditionally packaged status of CPT code 0174T. As discussed extensively in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66667), after thorough discussion with the APC Panel and repeated review by our medical advisors, we continue to believe that these codes are appropriately unconditionally packaged. Because CPT codes 0174T and 0175T are supportive ancillary services that fit into the ''image processing'' category, we packaged payment for all image processing services in CY 2008, and we proposed to continue packaging all image processing services in CY 2009. We believe it is appropriate to maintain the packaged status of these codes because we received no additional data subsequent to the CY 2009 OPPS/ASC proposed rule that convinced us to change this policy.

An image processing service processes and integrates diagnostic test data that were captured during another independent procedure. Computer-aided detection services, which incorporate pattern recognition and image analysis of x-rays or other radiologic studies to aid radiologists in the detection of abnormalities, meet this definition. Therefore, we continue to believe that computer-aided detection services fit into the image processing category, despite any additional requirements that may apply for FDA approval.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to unconditionally package payment for chest x-ray CAD services described by CPT codes 0174T and 0175T for CY 2009. We are also finalizing our CY 2009 proposal, without modification, to unconditionally package payment for all image processing services.

Comment: Several commenters were concerned that some ''stand-alone'' procedures and services were proposed with status indicator ''N'' for the CY 2009 OPPS. When a hospital provides these services without any other service on the same day, these commenters pointed out that the hospital would not receive any payment for the services. Several commenters cited CPT code 77014 (Computed tomography guidance for placement of radiation therapy fields) as an example of a service that may be performed by Hospital A, while Hospital B provides the associated main independent procedure, the radiation therapy. The commenters noted that in the situation described, Hospital A would not receive any payment and Hospital B would receive payment that included payment for CPT code 77014 and, therefore, they requested that CMS treat CPT code 77014 as a conditionally packaged code, rather than an unconditionally packaged code. Other commenters described a clinical scenario in which one hospital would provide both services, but on different days, and requested that CMS assign a conditionally packaged status indicator to CPT code 77014 so that the hospital would receive payment for services provided on each day. One commenter also noted that it is possible for Hospital A to provide guidance services associated with placement of a breast wire or clips prior to the breast biopsy procedure that would be performed by Hospital B. The latter commenter stated

that in many instances, Hospital A would not provide the services under arrangement with Hospital B. The commenter further noted that if Hospital A were to bill the service to CMS, the bill would be returned to the provider because there would be no separately payable service on the claim.

Response: CMS medical advisors reevaluated every unconditionally packaged HCPCS code, as well as clinical scenarios related to those packaged codes, and determined that the unconditionally packaged status of every code is appropriate, except for CPT code 76936 (Ultrasound guided compression repair of arterial pseudoaneurysm or arteriovenous fistulae (includes diagnostic ultrasound evaluation, compression of lesion and imaging)).

For CY 2008, we unconditionally packaged CPT code 76936 because we classified it as a guidance service, and we packaged all guidance services beginning in CY 2008. We did not receive any public comments on the CY 2008 OPPS/ASC proposed rule requesting that we unpackage payment for this code. However, because this code describes a vascular repair procedure, of which image guidance is a component, upon further examination we believe that separate payment is the most appropriate payment methodology for the service. Therefore, for CY 2009, CPT code 76936 is assigned to APC 0096 (Non-Invasive Vascular Studies), with status indicator ''S.''

CMS medical advisors specifically reviewed the clinical scenarios surrounding CPT code 77014 offered by the commenters and determined that its unconditional packaged status is appropriate. If we were to treat CPT code 77014 as a conditionally packaged code, we would create an incentive for a hospital to provide this service on a different day than other services related to radiation therapy, whereas when this code is unconditionally packaged, the hospital has an incentive to provide the service described by CPT code 77014 at the most appropriate time, from the perspective of the patient and hospital. We believe that it would be uncommon for one hospital to provide the guidance service described by CPT code 77014 and another hospital to provide radiation therapy. Section 1866 of the Act sets forth the requirements for provider enrollment. More specifically, section 1866(a)(1)(H) of the Act states, ''in the case of hospitals which provide services for which payment may be made under this title and in the case of critical access hospitals which provide critical access hospital services, to have all items and services (other than physicians' services as defined in regulations for purposes of section 1862(a)(14), and other than services described by section 1861(s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist) (I) that are furnished to an individual who is a patient of the hospital, and (II) for which the individual is entitled to have payment made under this title, furnished by the hospital or otherwise under arrangements (as defined in section 1861(w)(1)) made by the hospital.'' In other words, each Medicare-participating hospital must agree to furnish directly all covered nonphysician facility services required by its patients (inpatients and outpatients) or to have the services furnished under arrangement (as defined in section 1861(w)(1) of the Act). In addition, § 410.27(a)(1)(i) through (iii) further requires that payment is made for hospital outpatient services (1) furnished by or under arrangement by the hospital, (2) as an integral though incidental part of the physician's services, and (3) in the hospital or at a department of the provider that has provider-based status in relation to the hospital, as defined in § 413.65. That means when a patient requires a particular service ordered by the physician, such as the radiation therapy services in question, the hospital would be responsible for ensuring that service is provided directly or that the hospital arranges for the service to be provided in that hospital or in a provider-based department of that hospital. Both the independent service, here the radiation therapy, and the dependent guidance service are necessary to perform the radiation therapy. If the services cannot all be provided by the hospital, whether directly or under arrangement as required in § 410.27(a), then the hospital would discharge the patient and refer that patient to another provider to receive the services.

If one hospital provided the service described by CPT code 77014 on one day, and the same hospital provided radiation therapy services on another day, as long as both services were reported on one claim, we would package payment across the dates of service. This was discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66637) in the context of diagnostic radiopharmaceuticals that may be provided on a day prior to an independent procedure. In light of the ability of ''natural'' singles claims to package costs across days, we believe that our standard OPPS ratesetting methodology of using median costs calculated from claims data would adequately capture the costs of CPT code 77014 associated with radiation therapy services that are not provided on the same date of service.

CMS medical advisors also reviewed the clinical scenarios surrounding CPT codes 19290 (Preoperative placement of needle localization wire, breast); 19291 (Preoperative placement of needle localization wire, breast; each additional lesion) (List separately in addition to code for primary procedure)); and 19295 (Image guided placement, metallic localization clip, percutaneous, during breast biopsy (List separately in addition to code for primary procedure)). Our rationale for unconditionally packaging this service is parallel to the rationale described for unconditionally packaging CPT code 77014. As stated above, we believe that it would be very unlikely that one hospital would perform the preoperative wire placement in the breast and then send the patient to another facility for the breast biopsy procedure both because it would be potentially difficult and uncomfortable for the beneficiary and because this care pattern would not conform to the requirements of the statute and regulations that the hospital must furnish directly or arrange to have furnished all services required by its patients.

In response to the commenter who stated that a claim without any separately payable services would be returned to the provider, as we stated in the CY 2007 OPPS final rule with comment period (71 FR 67995), claims with only packaged codes and no separately payable codes are processed by the I/OCE and rejected for payment, but are included in the national claims history file that we analyze and use to set payment rates. Therefore, we have hospital claims data for packaged codes that are provided without any separately payable service.

After consideration of the public comments received, we are finalizing our CY 2009 proposal to unconditionally package all HCPCS codes for services assigned status indicator ''N'' in Addendum B to this final rule with comment period, with modification to provide separate payment for CPT code 76936, assigned status indicator ''S,'' through APC 0096 for CY 2009.

Comment: Many commenters requested separate payment for CPT code 31620 (Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List

separately in addition to code for primary procedure)). The commenters noted that the payment rate for performing a bronchoscopy with EBUS dropped significantly between CYs 2007 and 2009, from approximately $2,500 to approximately $700, and they are concerned that beneficiary' access to care will be limited if hospitals are no longer financially able to offer this important clinical tool. The commenters indicated that EBUS is only represented on a small portion of bronchoscopy claims. The commenters believed that packaging payment for EBUS will result in more mediastinoscopies, a more invasive and costly procedure. One commenter asserted that EBUS should be unpackaged to correct the violation of the 2 times rule for the APCs (specifically APC 0076 (Level I Endoscopy Lower Airway)) that contain bronchoscopy procedures. The commenters recommended various ideas for creation of composite APCs that would include payment for EBUS, when performed. Several commenters requested that CMS unpackage payment for certain ultrasound guidance services, for similar reasons.

Response: We do not agree that beneficiary access to care will be harmed or that the number of mediastinoscopies will increase as a result of packaging payment for CPT code 31620. We believe that packaging created incentives for hospitals and physician partners to work together to establish appropriate protocols that will eliminate unnecessary services where they exist and institutionalize approaches to providing necessary services more efficiently. If this review results in the concentration of some services in a reduced number of hospitals in the community, we believe that the quality of care and hospital efficiency may both be enhanced as a result. The medical literature shows that concentration of services in certain hospitals often results in both greater efficiency and higher quality of care for patients. As we have stated previously, the median cost for a particular independent procedure generally will be higher as a result of added packaging, but also could change little or be lower because median costs typically do not reflect small distributional changes and because changes to the packaged HCPCS codes affect both the number and composition of single bills and the mix of hospitals contributing those single bills. In this case, our data indicate increased packaged costs associated with the services into which CPT code 31620 is packaged, ultimately increasing the APC payment rates for bronchoscopy procedures. We will include the CY 2008 claims data for CPT code 31620 from its first year of packaged payment in our analysis recommended by the APC Panel to assess changes in utilization patterns that may accompany packaged payment.

Regarding the comment about the 2 times rule violations for bronchoscopy APCs, because we have traditionally paid for a service package under the OPPS as represented by a HCPCS code for the major procedure that is assigned to an APC group for payment, we assess the applicability of the 2 times rule to services at the HCPCS code level, not at a more specific level based on the individual intraoperative service that may be performed during an independent service reported with a HCPCS code for the major service. If the use of a very expensive intraoperative service in a clinical scenario causes a specific procedure to be much more expensive for the hospital than the APC payment, we consider such a case to be the natural consequence of a prospective payment system that anticipates that some cases will be more costly and other less costly than the procedure payment. In addition, very high cost cases could be eligible for outlier payment. Decisions about packaging and bundling payment involve a balance between ensuring some separate payment for individual services and establishing incentives for efficiency through larger units of payment.

While the proposed configuration of APC 0076 did not violate the 2 times rule, we note that we have slightly reconfigured APC 0076 for this final rule with comment period as a result of our medical advisors' regular review of all APCs for clinical and resource homogeneity, using updated final rule data. Specifically, CPT code 31615 (Tracheobronchoscopy through established tracheostomy incision) is reassigned from APC 0076 to APC 0252 (Level III ENT Procedures) for CY 2009.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification to package payment for EBUS and ultrasound guidance services for CY 2009.

We have responded to public comments related to potential composite APCs in section II.A.2.e. of this final rule with comment period.

B. 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. Section 1833(t)(3)(C)(iv) of the Act provides that, for CY 2009, the update 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 final hospital market basket increase for FY 2009 published in the IPPS final rule on August 19, 2008 is 3.6 percent (73 FR 48759). To set the OPPS conversion factor for CY 2009, we increased the CY 2008 conversion factor of $63.694, as specified in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66677), by 3.6 percent. Hospitals that fail to meet the reporting requirements of the Hospital Outpatient Quality Data Reporting (HOP QDRP) program are subject to a reduction of 2.0 percentage points from the market basket update 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 final rule with comment period.

In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the conversion factor for CY 2009 to ensure that any revisions we are making to our updates for a revised wage index and rural adjustment are made on a budget neutral basis. We calculated an overall budget neutrality factor of 1.0013 for wage index changes by comparing total payments from our simulation model using the FY 2009 IPPS final wage index values as finalized to those payments using the current (FY 2008) IPPS wage index values. For CY 2009, we did not propose a change to our rural adjustment policy. Therefore, the budget neutrality factor for the rural adjustment is 1.000.

For this final rule with comment period, we estimated that allowed pass-through spending for both drugs and biologicals and devices for CY 2009 would equal approximately $33.3 million, which represents 0.11 percent of total projected OPPS spending for CY 2009. Therefore, the conversion factor was also adjusted by the difference between the 0.09 percent pass-through dollars set aside for CY 2008 and the 0.11 percent estimate for CY 2009 pass-through spending. Finally, estimated payments for outliers remain at 1.0 percent of total OPPS payments for CY 2009.

The market basket increase update factor of 3.6 percent for CY 2009, the required wage index budget neutrality adjustment of approximately 1.0013, and the adjustment of 0.02 percent of projected OPPS spending for the difference in the pass-through set aside resulted in a full market basket conversion factor for CY 2009 of

$66.059. To calculate the CY 2009 reduced market basket conversion factor for those hospitals that fail to meet the requirements of the HOP QDRP for the full CY 2009 payment update, we made all other adjustments discussed above, but used a reduced market basket increase update factor of 1.6 percent. This resulted in a reduced market basket conversion factor for CY 2009 of $64.784 for those hospitals that fail to meet the HOP QDRP requirements.

Comment: One commenter requested that CMS update the conversion factor using the final FY 2009 IPPS market basket increase update factor of 3.6 percent rather than the proposed FY 2009 IPPS market basket increase update factor of 3.0 percent.

Response: We agree and have applied the final FY 2009 IPPS market basket increase update factor of 3.6 percent to calculate the CY 2009 OPPS conversion factor. When we developed the CY 2009 OPPS/ASC proposed rule, the FY 2009 IPPS market basket increase update factor of 3.6 percent had not yet been finalized. Therefore, we could not use it to update the proposed CY 2009 OPPS conversion factor. As is our longstanding policy, when developing the proposed OPPS update for a given calendar year, we use the most current IPPS market basket update factor available for the year applicable to the OPPS update and adopt that finalized IPPS value when we develop the final rule with comment period for the OPPS update.

After consideration of the public comment received, we are finalizing our CY 2009 proposal, without modification, to update the conversion factor by the FY 2009 IPPS market basket increase update factor of 3.6 percent, resulting in a final full conversion factor of $66.059 and in a reduced conversion factor of $64.784 for those hospitals that fail to meet the HOP QDRP reporting requirements.

C. 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 final rule with comment period.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that 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 did not propose to revise this policy for the CY 2009 OPPS. We refer readers to section II.G. of this final rule with comment period for a description and example of how the wage index for a particular hospital is used to determine the payment for the hospital.

As discussed in section II.A.2.c. of this final rule with comment period, for estimating national median APC costs, we standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2009 pre-reclassified wage indices 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 indices as the wage indices for adjusting the OPPS standard payment amounts for labor market differences. Thus, the wage index that applies to a particular acute short-stay hospital under the IPPS will 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 proposed to use the final FY 2009 version of the IPPS wage indices used to pay IPPS hospitals to adjust the CY 2009 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).

We note that the final FY 2009 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 to different geographic areas, rural floor provisions and the accompanying budget neutrality adjustment, 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 2009 IPPS final rule (73 FR 48563 through 48592) and to the **Federal Register** notice published subsequent to that final rule on October 3, 2008 (73 FR 57888) for a detailed discussion of recent changes to the FY 2009 IPPS wage indices, including adoption of a 3-year transition from a national budget neutrality adjustment to a State-level budget neutrality adjustment for the rural and imputed floors. 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 indices that we proposed to adopt in the CY 2009 OPPS/ASC proposed rule include all reclassifications that are approved by the Medicare Geographic Classification Review Board (MGCRB) for FY 2009. We note that reclassifications under section 508 of Public Law 108–173 and certain special exception reclassifications that were extended by section 106(a) of the MIEA-TRHCA and section 117(a)(1) of the MMSEA (Pub. L. 110–173) were set to terminate September 30, 2008. Section 117(a)(2) of the MMSEA also extended certain special exception reclassifications. On February 22, 2008, we published a notice in the **Federal Register** (73 FR 9807) that indicated how we are implementing section 117(a) of the MMSEA under the IPPS. We also issued a joint signature memorandum on January 28, 2008, that explained how section 117 of the MMSEA would apply to the OPPS. As we stated in that memorandum, most of the reclassifications extended by the MMSEA would expire September 30, 2008, for both the IPPS and the OPPS (with OPPS hospitals reverting to a previous reclassification or home area wage index from October 1, 2008 to December 31, 2008). However, because we implemented the special exception wage indices for certain hospitals on a calendar year cycle for OPPS, we extended special exception wage indices through December 31, 2008, in order to give these hospitals the special exception wage indices under the OPPS

for the same time period as under the IPPS.

Since issuance of the CY 2009 OPPS/ASC proposed rule, section 124 of Public Law 110–275 (MIPPA) further extended geographic reclassifications under section 508 and certain special exception reclassifications until September 30, 2009. We did not make any proposals related to these provisions for the CY 2009 OPPS wage indices in our proposed rule, since the MIPPA was enacted after issuance of the CY 2009 OPPS/ASC proposed rule. In accordance with section 124 of Public Law 110–275, for CY 2009, we are adopting all section 508 geographic reclassifications through September 30, 2009. Similar to our treatment of section 508 reclassifications extended under the MMSEA as described above, hospitals with section 508 reclassifications will revert to their home area wage index, with out-migration adjustment if applicable, from October 1, 2009, to December 31, 2009. As we did for CY 2008, we also are extending the special exception wage indices for certain hospitals through December 31, 2009, 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 **Federal Register** notice published subsequent to the FY 2009 IPPS final rule for a detailed discussion of the changes to the wage indices as required by section 124 of the Public Law 110–275 (73 FR 57888).

For purposes of the OPPS, we proposed to continue our policy in CY 2009 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** notice that provides final FY 2009 IPPS wage indices published subsequent to the FY 2009 IPPS final rule (73 FR 57988) 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 final rule with comment period, with the addition of non-IPPS hospitals that will receive the section 505 out-migration adjustment under the CY 2009 OPPS.

As stated earlier in this section, we continue to believe that using the IPPS wage indices 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 proposed to use the final FY 2009 IPPS wage indices for calculating the OPPS payments in CY 2009. With the exception of the out-migration wage adjustment table (Addendum L to this final rule with comment period), which includes non-IPPS hospitals paid under the OPPS, we are not reprinting the finalized FY 2009 IPPS wage indices referenced in this discussion of the wage index. We refer readers to the CMS Web site for the OPPS at: *http://www.cms.hhs.gov/providers/hopps.* At this link, readers will find a link to the final FY 2009 IPPS wage index tables as finalized.

Comment: Several commenters supported the CMS proposal to extend the IPPS wage indices to the OPPS in CY 2009 as we have done in previous years. One commenter praised the adoption of reclassifications approved by the MGCRB. Another commenter supported the extension of the special exception reclassifications for certain hospitals through December 31, 2008 for the OPPS.

Response: We appreciate the support expressed by the commenters for our proposed CY 2009 wage index policies, as well as our CY 2008 policy that extended the special exception wage indices through December 31, 2008. As discussed earlier, in implementing section 124 of Public Law 110–275, we also are extending the special exception wage indices through December 31, 2009, under the OPPS. With regard to adopting reclassifications approved by the MGCRB, we note that under the OPPS we adopt the IPPS wage indices in their entirety, including wage index reclassifications. Therefore, any reclassifications approved for a hospital would apply to payment under both the IPPS and the OPPS.

Comment: One commenter opposed CMS' implementation of the FY 2009 IPPS wage indices in the OPPS in light of the revisions to the reclassification average hourly wage comparison criteria, as finalized in the FY 2009 IPPS final rule. Specifically, the commenter suggested that CMS consider the redistributional effects of implementing the changes to the comparison threshold. In addition, the commenter stated that a change in the reclassification comparison criteria, coupled with CMS' implementation of a transitional within-State rural floor budget neutrality adjustment, could have a substantially negative effect on hospitals located in rural markets.

Response: We appreciate the comment concerning our revision to the reclassification average hourly wage comparison criteria as discussed in the FY 2009 IPPS final rule (73 FR 48568). Our consistent policy has been to adopt the IPPS fiscal year wage indices for use under the OPPS, including IPPS policy on geographic reclassification. While the commenter discussed the redistributional effects of changes made in the IPPS rulemaking process, the inherent policy rationales underlying such changes were not discussed. The policy rationales for an update to the geographic reclassification wage comparison criteria and budget neutrality for the rural and imputed floors were fully discussed during the FY 2009 IPPS rulemaking process, and hospitals had the opportunity to comment specifically on such policy rationales during that process.

Comment: One commenter expressed concern about the impact of the wage index on hospital payment for specific APCs. In particular, the commenter argued that 60 percent, the current percentage of the APC payment that is adjusted for variation in labor-related costs, is too large of a percentage for APCs that incorporate high cost technologies, implantable devices, and drugs, and instead suggested a labor rate split of 20 percent (based on the commenter's data) for APCs that include high device or supply costs. The commenter suggested a labor-related share of 20 percent for APCs 0107 (Insertion of Cardioverter-Defibrillator); 0108 (Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads); 0222 (Level II Implantation of Neurostimulator); 0225 (Implantation of Neurostimulator Electrodes, Cranial Nerve); 0227 (Implantation of Drug Infusion Device); 0315 (Level III Implantation of Neurostimulator); 0418 (Insertion of Left Ventricular Pacing Elect.); 0654 (Insertion/Replacement of a Permanent Dual Chamber Pacemaker); 0655 (Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker); 0656 (Transcatheter Placement of Intracoronary Drug-Eluting Stents); and others that CMS believes would meet the criteria discussed by the commenter.

Moreover, regarding the effects of wage adjustment on hospital payment for certain services, MedPAC noted that the effect of charge compression on OPPS payment for services where devices make up a large percentage of the costs of the service tend to be exacerbated among hospitals in low-wage areas and counteracted in high-wage areas because CMS wage adjusts a portion of the device cost, which typically exceeds 40 percent of the APC payment. The MedPAC suggested that CMS overadjusts for the labor costs in these services and stated its plan to

evaluate CMS' method for adjusting payments for variations in labor costs.

Response: We do not believe it is appropriate to vary the percentage of the national payment that is wage adjusted for different services provided under the OPPS. Such a change could not be considered without first assessing its impact on the OPPS labor-related share calculation. The OPPS labor-related share of 60 percent was determined through regression analyses conducted for the initial OPPS proposed rule (63 FR 47581) and recently confirmed for the CY 2006 OPPS final rule with comment period (70 FR 68556). The labor-related share is a provider-level adjustment based on the relationship between the labor input costs and a provider's average OPPS unit cost, holding all other things constant. While numerous individual services may have variable labor shares, these past analyses identified 60 percent as the appropriate labor-related share across all types of outpatient services and are the basis for our current policy. The provider-level adjustment addresses payment for all services paid under the OPPS. We look forward to reviewing the results of MedPAC's evaluation of the CMS method for adjusting payment for variation in labor costs in light of differences in labor-related costs for device-implantation services, as well as any recommendations it may provide regarding the OPPS wage adjustment policy.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to use the final FY 2009 IPPS wage indices to adjust the OPPS standard payment amounts for labor market differences.

D. Statewide Average Default CCRs

CMS uses CCRs to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS, in addition to adjusting hospitals' charges reported on claims to costs. Some hospitals do not have a CCR 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). As proposed, in this final rule with comment period, we are updating the default ratios for CY 2009 using the most recent cost report data, and we are codifying our policies for using the default ratios for hospitals that do not have a CCR for outlier payments specifically. We refer readers to section II.F. of this final rule with comment period where we discuss our final policy for default CCRs, including setting the ceiling threshold for a valid CCR, as part of our broader implementation of an outlier reconciliation process similar to that implemented under the IPPS.

For CY 2009, we used 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. Table 9 published in the CY 2009 OPPS/ASC proposed rule listed the proposed CY 2009 default urban and rural CCRs by State and compared them to last year's default CCRs. These CCRs are the ratio of total costs to total charges from each hospital's most recently submitted cost report, for those cost centers relevant to outpatient services 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 costs and charges from the most recent pair of final settled and submitted cost reports. We then weighted each hospital's CCR by claims volume corresponding to the year of the majority of cost reports used to calculate the overall CCR. We refer readers to section II.E. of 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 trimming criteria.

For the CY 2009 OPPS/ASC proposed rule, approximately 38 percent of the submitted cost reports represented data for cost reporting periods ending in CY 2005 and 60 percent were for cost reporting periods ending in CY 2006. We have since updated the cost report data we use to calculate CCRs with additional cost reports ending in CYs 2006 and 2007. For this final rule with comment period, 53 percent of the submitted cost reports utilized in the default ratio calculation are for CY 2006 and 46 percent are for CY 2007. For Maryland, we use 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 between CYs 2008 and 2009 are modest and the few significant changes are associated with a small number of hospitals.

We did not receive any public comments concerning our CY 2009 proposal to apply 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. Public comments on setting the threshold for determining a valid CCR are discussed in section II.F. of this final rule with comment period. Therefore, we are finalizing the statewide average default CCRs as shown in Table 11 below for OPPS services furnished on or after January 1, 2009.

TABLE 11—CY 2009 STATEWIDE AVERAGE CCRS

State	Urban/rural	Final CY 2009 default CCR	Previous default CCR (CY 2008 OPPS final rule)
ALASKA	RURAL	0.562	0.537
ALASKA	URBAN	0.345	0.351
ALABAMA	RURAL	0.221	0.228
ALABAMA	URBAN	0.202	0.213
ARKANSAS	RURAL	0.256	0.266
ARKANSAS	URBAN	0.268	0.270
ARIZONA	RURAL	0.267	0.264

TABLE 11—CY 2009 STATEWIDE AVERAGE CCRS—Continued

State	Urban/rural	Final CY 2009 default CCR	Previous default CCR (CY 2008 OPPS final rule)
ARIZONA	URBAN	0.226	0.232
CALIFORNIA	RURAL	0.219	0.232
CALIFORNIA	URBAN	0.218	0.218
COLORADO	RURAL	0.346	0.355
COLORADO	URBAN	0.248	0.254
CONNECTICUT	RURAL	0.372	0.391
CONNECTICUT	URBAN	0.322	0.339
DISTRICT OF COLUMBIA	URBAN	0.329	0.346
DELAWARE	RURAL	0.302	0.302
DELAWARE	URBAN	0.349	0.400
FLORIDA	RURAL	0.204	0.219
FLORIDA	URBAN	0.189	0.198
GEORGIA	RURAL	0.267	0.279
GEORGIA	URBAN	0.251	0.269
HAWAII	RURAL	0.367	0.373
HAWAII	URBAN	0.344	0.317
IOWA	RURAL	0.439	0.349
IOWA	URBAN	0.294	0.325
IDAHO	RURAL	0.449	0.445
IDAHO	URBAN	0.419	0.414
ILLINOIS	RURAL	0.280	0.286
ILLINOIS	URBAN	0.266	0.271
INDIANA	RURAL	0.298	0.313
INDIANA	URBAN	0.295	0.301
KANSAS	RURAL	0.300	0.318
KANSAS	URBAN	0.238	0.240
KENTUCKY	RURAL	0.236	0.244
KENTUCKY	URBAN	0.255	0.262
LOUISIANA	RURAL	0.283	0.271
LOUISIANA	URBAN	0.258	0.277
MARYLAND	RURAL	0.303	0.308
MARYLAND	URBAN	0.276	0.284
MASSACHUSETTS	URBAN	0.328	0.338
MAINE	RURAL	0.452	0.433
MAINE	URBAN	0.428	0.424
MICHIGAN	RURAL	0.317	0.331
MICHIGAN	URBAN	0.321	0.318
MINNESOTA	RURAL	0.488	0.499
MINNESOTA	URBAN	0.348	0.342
MISSOURI	RURAL	0.269	0.289
MISSOURI	URBAN	0.282	0.292
MISSISSIPPI	RURAL	0.261	0.267
MISSISSIPPI	URBAN	0.209	0.217
MONTANA	RURAL	0.455	0.453
MONTANA	URBAN	0.439	0.450
NORTH CAROLINA	RURAL	0.272	0.286
NORTH CAROLINA	URBAN	0.292	0.321
NORTH DAKOTA	RURAL	0.369	0.379
NORTH DAKOTA	URBAN	0.354	0.378
NEBRASKA	RURAL	0.345	0.347
NEBRASKA	URBAN	0.283	0.290
NEW HAMPSHIRE	RURAL	0.350	0.375
NEW HAMPSHIRE	URBAN	0.296	0.337
NEW JERSEY	URBAN	0.257	0.276
NEW MEXICO	RURAL	0.263	0.275
NEW MEXICO	URBAN	0.328	0.353
NEVADA	RURAL	0.312	0.329
NEVADA	URBAN	0.192	0.200
NEW YORK	RURAL	0.412	0.417
NEW YORK	URBAN	0.388	0.402
OHIO	RURAL	0.353	0.354
OHIO	URBAN	0.258	0.268
OKLAHOMA	RURAL	0.278	0.288
OKLAHOMA	URBAN	0.238	0.245
OREGON	RURAL	0.318	0.321
OREGON	URBAN	0.374	0.366
PENNSYLVANIA	RURAL	0.284	0.298
PENNSYLVANIA	URBAN	0.232	0.241
PUERTO RICO	URBAN	0.519	0.474
RHODE ISLAND	URBAN	0.294	0.308

TABLE 11—CY 2009 STATEWIDE AVERAGE CCRS—Continued

State	Urban/rural	Final CY 2009 default CCR	Previous default CCR (CY 2008 OPPS final rule)
SOUTH CAROLINA	RURAL	0.242	0.258
SOUTH CAROLINA	URBAN	0.240	0.244
SOUTH DAKOTA	RURAL	0.336	0.334
SOUTH DAKOTA	URBAN	0.267	0.289
TENNESSEE	RURAL	0.244	0.256
TENNESSEE	URBAN	0.221	0.241
TEXAS	RURAL	0.257	0.271
TEXAS	URBAN	0.238	0.242
UTAH	RURAL	0.413	0.416
UTAH	URBAN	0.430	0.406
VIRGINIA	RURAL	0.257	0.268
VIRGINIA	URBAN	0.266	0.275
VERMONT	RURAL	0.406	0.416
VERMONT	URBAN	0.422	0.340
WASHINGTON	RURAL	0.349	0.358
WASHINGTON	URBAN	0.342	0.368
WISCONSIN	RURAL	0.399	0.384
WISCONSIN	URBAN	0.346	0.362
WEST VIRGINIA	RURAL	0.293	0.298
WEST VIRGINIA	URBAN	0.349	0.360
WYOMING	RURAL	0.418	0.449
WYOMING	URBAN	0.331	0.351

E. OPPS Payment to Certain Rural and Other Hospitals

1. Hold Harmless Transitional Payment Changes Made by Public Law 110–275 (MIPPA)

When the OPPS was implemented, every provider was eligible to receive an additional payment adjustment (called either transitional corridor payment or transitional outpatient payment (TOPS)) if the payments it received for covered OPD services under the OPPS were less than the payment 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 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 Public Law 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 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 Public Law 108–173, for rural hospitals having 100 or fewer beds and SCHs located in rural areas expired on December 31, 2005.

Section 5105 of Public Law 109–171 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 is less than the provider's pre-BBA amount, the amount of payment is increased by 95 percent of the amount of the difference between the two payment systems for CY 2006, by 90 percent of the amount of that difference for CY 2007, and by 85 percent of the amount of that difference for CY 2008.

For CY 2006, we implemented section 5105 of Public Law 109–171 through Transmittal 877, issued on February 24, 2006. In the Transmittal, we did not specifically address whether TOPs 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 Public Law 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 Public Law 109–171.

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

Comment: Several commenters supported the legislative extension of TOPs to small rural hospitals and small SCHs for services provided before January 1, 2010, under section 147 of Public Law 110–275.

Response: We appreciate the commenters' support.

In this final rule with comment period, we are revising §§ 419.70(d)(2) and (d)(4) and adding a new paragraph (d)(5) to incorporate the provisions of section 147 of Public Law 110–275. We note that our interpretation of the term ''beds,'' as is used in the regulation for determining the number of beds in a hospital, is consistent with how that term is defined in our established hold harmless policy in § 419.70, as stated in the April 7, 2000, OPPS final rule with comment period (65 FR 18501). In addition, while we were reviewing § 419.70(d)(2) in order to incorporate the change provided by section 147 of Pub. L. 110–275, we realized that our use of the word ''paragraph'' was incorrect. Specifically, the provision states that for covered hospital outpatient services furnished in a calendar year from January 1, 2006, through December 31, 2009, for which the prospective payment amount is less than the pre-BBA amount, the amount of payment under this paragraph is increased by the amount of the difference. We note that if the prospective payment amount is less than the pre-BBA amount, payments under this part (Part 419), not paragraph, are increased. Therefore, in order to more precisely capture our existing policy and to correct an inaccurate cross reference, we are substituting the word ''part'' for ''paragraph.''

In addition, in our review of § 419.70 to implement section 147 of Public Law 110–275, we discovered that the cross-references in paragraphs (e), (g), and (i) of § 419.70 were incorrect. Paragraph (e) defines the term ''prospective payment system amount'' which is used throughout § 419.70. However, the language in paragraph (e) incorrectly references ''this paragraph'' rather than ''this section.'' We are making a technical correction to this cross-reference to correct the error and to accurately reflect the current policy. In addition, paragraph (g) of § 419.70 states that ''CMS makes payments under this paragraph * * *'' Because paragraph (g) is intended to specify how additional OPPS payments will be made to hospitals and CMHCs that result from the application of the transitional adjustments set forth in the entire § 419.70, in this final rule with comment period, we are correcting the cross-reference in paragraph (g) by removing ''paragraph'' and replacing it with ''section'' to correct the error and to accurately reflect the current policy. Similarly, paragraph (i) of § 419.70 cross-references the additional payments as those made under paragraph (i) rather than as those made under the entire § 419.70. Therefore, in this final rule with comment period, we also are correcting this cross-reference error to read ''section'' to accurately reflect the current policy.

2. Adjustment for Rural SCHs Implemented in CY 2006 Related to Public Law 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 services paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of Public Law 108–173. Section 411 gave the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural and 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 drugs, biologicals, brachytherapy sources, and services 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 Public Law 105–33, a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating 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 again in CY 2008.

For the CY 2009 OPPS, we proposed to continue our current 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 drugs, biologicals, and services paid under the pass-through payment policy.

For CY 2009, we proposed to include brachytherapy sources in the group of services eligible for the 7.1 percent payment increase because we proposed to pay them for CY 2009 at prospective rates based on their median costs as calculated from historical claims data. However, subsequent to issuance of the CY 2009 OPPS/ASC proposed rule, section 142 of Public Law 110–275 amended section 1833(t)(16)(C) of the Act by extending payment for brachytherapy sources at charges adjusted to cost for services provided prior to January 1, 2010. Our consistent policy has been to exclude items paid at charges adjusted to cost from the 7.1 percent payment adjustment. Therefore, consistent with past policy, brachytherapy sources will not be eligible for the 7.1 percent payment adjustment for CY 2009.

Statutory provisions to pay for brachytherapy sources and other items under the OPPS at charges adjusted to cost have been common over the history of the OPPS. In the past, we updated the regulations at § 419.43(g)(4) each year to exclude those items paid at charges adjusted to cost by identifying those items specifically. However, for administrative ease and convenience, we are now updating § 419.43(g)(4) to specify in a general manner that items paid at charges adjusted to cost by application of a hospital-specific CCR are excluded from the percent payment adjustment in § 419.43(g)(2). We note that § 419.43(g)(4) currently specifically identifies devices or brachytherapy consisting of a seed or seeds (including a radioactive source) as being excluded from the payment adjustment in § 419.43(g)(2) (because they are paid at charges adjusted to cost). In addition, section 147 of Public Law 110–275 also provides that brachytherapy sources and therapeutic radiopharmaceuticals are paid at charges adjusted to cost for a specified time period. We believe that it would be administratively burdensome to amend the regulations in this final rule with comment period to specifically identify these items as exclusions and then to engage in notice and comment rulemaking to later delete their reference upon the sunset of the provision if we were to adopt a different payment methodology. As indicated above in this section, we believe that the most logical approach is to exclude all

items paid at charges adjusted to cost as determined by hospital-specific CCRs.

In addition, as noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41461), 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, and provider information.

Comment: Several commenters supported the proposed 7.1 percent payment adjustment for rural SCHs. The commenters further requested that CMS finalize the proposal to apply the 7.1 percent payment adjustment to rural SCHs for CY 2009 despite the extension of TOPs to small SCHs for CY 2009. The commenters noted that the 7.1 percent adjustment and TOPs for CY 2009 apply to classes of hospitals that only partially overlap, specifically, the 7.1 percent adjustment applies to rural SCHs of any size while TOPs apply to all small SCHs (urban and rural) and small rural hospitals. In addition, the commenters stated that the purpose of the 7.1 percent adjustment is to compensate rural SCHs because they are costlier than other classes of hospitals, while the purpose of TOPs is to compensate certain hospitals for some of the money that these hospitals would otherwise have received for hospital outpatient services under a cost-based system.

Response: We will continue to apply the 7.1 percent payment adjustment to rural SCHs and provide TOPS to small SCHs (including EACHs) and small rural hospitals for CY 2009. We acknowledge that small rural SCHs are potentially eligible for both the 7.1 percent payment adjustment and TOPs, assuming all eligibility criteria are met.

Comment: One commenter requested that CMS extend the 7.1 percent payment adjustment to all SCHs, not just rural SCHs, under the equitable adjustment authority in section 1833(t)(2)(E) of the Act. The commenter described the necessary access to services that urban SCHs provide and highlighted the fact that both urban and rural SCHs have been recognized for special protections by Congress in other payment systems because they are the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The commenter also referenced a comment and data analysis that the commenter previously submitted to CMS in response to the CY 2006 OPPS proposed rule.

Response: As we have noted previously in response to a similar comment in the CY 2006 OPPS final rule with comment period (70 FR 68560 and 68561), the statutory authority for the rural adjustment relies upon a comparison of costs between urban and rural hospitals. Extending this adjustment to urban SCHs under our equitable adjustment authority would require urban SCHs to demonstrate strong empirical evidence that they are significantly more costly than other urban hospitals. We could not find any strong empirical evidence suggesting that urban SCHs are significantly more costly than other urban hospitals. In the CY 2006 OPPS final rule with comment period, we noted that urban SCHs' costs closely resembled urban hospitals' costs. While some urban SCHs may have unit costs as high as those of rural SCHs, many clearly did not. Accordingly, we are not adopting the commenters' suggestions to extend the rural adjustment to urban SCHs.

Comment: Several commenters requested that CMS provide adequate notice if the Agency plans to reassess the 7.1 percent adjustment in a future year. One commenter requested that CMS provide adequate notice and a comment period prior to applying a new adjustment, particularly if a decrease in the adjustment were to be proposed. Another commenter requested that CMS provide notice at least 12 months prior to implementing a change in the adjustment, to allow hospitals time to adjust their annual budget, of which expected payment is a key component.

Response: As noted earlier, 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, and provider information. According to our usual practice, we would perform the initial analysis on the most complete claims data available at the time the proposed rule is published. We would propose a new adjustment for rural hospitals or some class of rural hospitals, if appropriate, with an expected implementation date of January 1 of the next calendar year, because the annual proposed rule is the means we use to propose OPPS updates and changes in policies for the upcoming calendar year. Upon review of the public comments that we would expect to receive and our analysis of fully complete claims data, we would finalize a payment adjustment, if appropriate, effective January 1 of the next calendar year.

After consideration of the pubic comments received, we are finalizing our CY 2009 proposal, without modification, to apply the 7.1 percent payment adjustment to rural SCHs for all services and procedures paid under the OPPS in CY 2009, excluding drugs, biologicals, services paid under the pass-through payment policy, and items paid at charges adjusted to cost. We are revising 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.

F. Hospital Outpatient Outlier Payments

1. Background

Currently, the OPPS pays outlier payments on a service-by-service basis. For CY 2008, 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 $1,575 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 a hospital 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. This outlier payment has historically been considered a final payment by longstanding OPPS policy.

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. An accounting error for CYs 2005, 2006, and 2007 inflated CMS' estimates of OPPS expenditures, which led us to underestimate outlier payment as a percentage of total OPPS spending in prior rules. Total OPPS expenditures have been revised downward, and we have accordingly revised our outlier payment estimates. We further note that the CY 2005 outlier payment estimate included in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010) has not changed based on revised spending estimates. However, we previously stated that CY 2006 outlier payment was equal to 1.1 percent of OPPS expenditures for CY 2006 (72 FR 66685), but based on our revised numbers, actual outlier payments are equal to approximately 1.3 percent of CY 2006 OPPS expenditures. In the CY 2009 OPPS/ASC proposed rule (73 FR 41462), we estimated total outlier payments as a percent of total CY 2007 OPPS payment, using available CY 2007 claims and the revised OPPS expenditure estimate, to be approximately 0.9 percent. For CY 2007, the estimated outlier payment was set at

1.0 percent of the total aggregated OPPS payments. Having all CY 2007 claims, we continue to observe outlier payments of 0.9 percent of the total aggregated OPPS payment. Therefore, for CY 2007 we paid approximately 0.1 percent less than the CY 2007 outlier target of 1.0 percent of the total aggregated OPPS payments.

As explained in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66685), we set our projected target for aggregate outlier payments at 1.0 percent of the aggregate total payments under the OPPS for CY 2008. The outlier thresholds were set so that estimated CY 2008 aggregate outlier payments would equal 1.0 percent of the aggregate total payments under the OPPS. Using the same set of CY 2007 claims and CY 2008 payment rates, we currently estimate that the outlier payments for CY 2008 would be approximately 0.73 percent of the total CY 2008 OPPS payments. The difference between 1.0 percent and 0.73 percent is reflected in the regulatory impact analysis in section XXIII.B. of this final rule with comment period. We note that we provide estimated CY 2009 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

In the CY 2009 OPPS/ASC proposed rule (73 FR 41462), we proposed 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 in CY 2009. We proposed that a portion of that 1.0 percent, specifically 0.07 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 of 3.40 times the CY 2009 PHP APC payment rates, as a proportion of all payments dedicated to outlier payments. For further discussion of CMHC outlier payments, we refer readers to section X.D. of this final rule with comment period.

To ensure that the estimated CY 2009 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we proposed that the hospital outlier threshold be set so that outlier payments would be triggered when the cost of furnishing a service or procedure by a hospital exceeds 1.75 times the APC payment amount and exceeds the APC payment rate plus an $1,800 fixed-dollar threshold (73 FR 41462). This proposed threshold reflected the methodology discussed below in this section, as well as the proposed APC recalibration for CY 2009.

We calculated the fixed-dollar threshold for the CY 2009 OPPS/ASC proposed rule using largely the same methodology as we did in CY 2008. For purposes of estimating outlier payments for the CY 2009 OPPS/ASC proposed rule, we used the CCRs available in the April 2008 update to the Outpatient Provider Specific File (OPSF). The OPSF contains provider specific data, such as the most current CCR, which is 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 the CY 2009 OPPS/ASC proposed rule, we used CY 2007 claims to model the CY 2009 OPPS. In order to estimate the CY 2009 hospital outlier payments for the CY 2009 OPPS/ASC proposed rule, we inflated the charges on the CY 2007 claims using the same inflation factor of 1.1204 that we used to estimate the IPPS fixed-dollar outlier threshold for the FY 2009 IPPS proposed rule. For 1 year, the inflation factor we used was 1.0585. The methodology for determining this charge inflation factor was discussed in the FY 2009 IPPS proposed rule (73 FR 23710 through 23711) and the FY 2009 IPPS final rule (73 FR 48763). 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 routine service cost centers, hospitals use the same cost centers to capture costs and charges across 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 may systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we proposed to apply the same CCR inflation adjustment factor that we proposed to apply for the FY 2009 IPPS outlier calculation to the CCRs used to simulate the CY 2009 OPPS outlier payments that determined the fixed-dollar threshold. Specifically, for CY 2009, we proposed to apply an adjustment of 0.9920 to the CCRs that were in the April 2008 OPSF to trend them forward from CY 2008 to CY 2009. The methodology for calculating this adjustment is discussed in the FY 2009 IPPS proposed rule (73 FR 23710 through 23711) and the FY 2009 IPPS final rule (73 FR 48763).

Therefore, to model hospital outliers for the CY 2009 OPPS/ASC proposed rule, we applied the overall CCRs from the April 2008 OPSF file after adjustment (using the proposed CCR inflation adjustment factor of 0.9920 to approximate CY 2009 CCRs) to charges on CY 2007 claims that were adjusted (using the proposed charge inflation factor of 1.1204 to approximate CY 2009 charges). We simulated aggregated CY 2009 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple 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 2009 OPPS payments. We estimated that a proposed fixed-dollar threshold of $1,800, 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 proposed to continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the fixed-dollar $1,800 threshold are met. For CMHCs, if a CMHC's cost for partial hospitalization exceeds 3.40 times the payment rate for APC 0172 (Level I Partial Hospitalization (3 services)) or APC 0173 (Level II Partial Hospitalization (4 or more services)), the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC payment rate.

New 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 performed 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 proposed that the hospitals' costs would be compared to the reduced payments for purposes of

outlier eligibility and payment calculation (73 FR 41462 through 41463). We believe no changes in the regulation text would be necessary to implement this policy because using the reduced payment for these outlier eligibility and payment calculations is contemplated in the current regulations at § 419.43(d). This proposal conformed to current practice under the IPPS in this regard. Specifically, under the IPPS, for purposes of determining the hospital's eligibility for outlier payments, the hospital's estimated operating costs for a discharge are compared to the outlier cost threshold based on the hospital's actual DRG payment for the case. For more information on the HOP QDRP, we refer readers to section XVI. of this final rule with comment period.

Comment: Several commenters supported the increase in the fixed-dollar threshold for CY 2009 in order to maintain the target outlier spending percentage of 1 percent of estimated total OPPS payments. Other commenters believed that the proposed outlier fixed-dollar threshold was inappropriate and should be reduced because CMS has not spent all the funds set aside for outlier payments in prior years. One commenter suggested that because the outlier pool has been greater than the need in prior years, CMS should either reduce the set-aside amount and retain those dollars in the OPPS ratesetting structure or lower the fixed-dollar threshold so that there is a zero-balance at the end of the year.

Another commenter suggested that outlier payments potentially be discontinued because certain organizations had not received outlier payments for some years. Several commenters did not support the proposed increase in the outlier threshold because they believed that consistent increases in the level of the outlier threshold reduced their hospitals' ability to capture additional reimbursement for high cost cases and put downward pressure on their hospitals' Medicare revenues.

A few commenters suggested that the fixed-dollar threshold remain at the CY 2008 level of $1,575. Some commenters recommended that the threshold be proportionally reduced based on the percentage difference between target and actual outlier spending. One commenter suggested that because CMS modeled only 0.8 percent of total payments made in outlier payments for CY 2008 in the impact table for the CY 2009 OPPS/ASC proposed rule (73 FR 41559), CMS should proportionally lower the proposed threshold to $1,440. Another commenter believed that the outlier pool should be increased to 2 percent of total OPPS payments, with corresponding thresholds of 1.5 times the APC payment amount and $1,175 based on their analysis on their hospital's costs and payments. Some commenters asked CMS to increase the OPPS outlier payment percentage from 50 percent to 80 percent to mirror inpatient outlier payments. One commenter requested that CMS increase outlier reimbursement to help teaching hospitals that provide complex outpatient services and incur significant costs. Another commenter suggested that the additional packaging by CMS would result in reduced outlier payments.

Response: In CY 2009, we proposed that outlier payments would be 1.0 percent of total estimated OPPS payments for outlier payments. In general, outlier payments are intended to ensure beneficiary access to services by having the Medicare program share in the financial loss incurred by a provider associated with individual, extraordinarily expensive cases. Because the OPPS makes separate payment for many individual services, there is less financial risk associated with the OPPS payment than, for example, with the DRG payment under the IPPS. Although some commenters suggested an increase to 2.0 percent of total estimated payment, we continue to believe that an outlier target payment percentage of 1.0 is appropriate because the OPPS largely pays hospitals a separate payment for most major services, which mitigates significant financial risk for most encounters, even complex ones. We acknowledge that teaching hospitals provide complex outpatient services and incur costs, but they also receive separate OPPS payment for most major services provided in a single encounter. Further, in a budget neutral system, increasing the percent of total estimated payments dedicated to outlier payments would reduce individual APC prospective payments.

Although the OPPS makes separate payment for most major services, we continue to believe that outlier payments are an integral component of the OPPS and that the small amount of OPPS payments targeted to outliers serve to mitigate the financial risk associated with extremely costly and complex services. In allocating only 1.0 percent of total estimated payments for outlier payments, the OPPS does not pay as much in total outlier payments as certain other payment systems. Instead, the OPPS concentrates a small amount of funds on extreme cases. For this reason, it is not unanticipated that some hospitals would not receive any OPPS outlier payments in any given year.

We believe that the estimated total CY 2009 outlier payments will meet the target of 1.0 percent of total estimated OPPS payments. Historically, OPPS outlier payments have exceeded the percentage of total estimated OPPS payments dedicated to outlier payments. Only for CY 2007 was actual outlier spending less than the target percentage of aggregate OPPS payments in that year, and only by 0.1 percent. We note that we estimated a larger difference between modeled outlier payment as a percentage of spending for CY 2007 and the CY 2007 1.0 percent outlay in the CY 2008 OPPS/ASC final rule with comment period. Further, the CY 2007 fixed-dollar threshold was higher, $1,825, than the CY 2008 threshold of $1,575, potentially increasing the likelihood that outlier payments would meet the target estimated spending percentage for CY 2008. Therefore, we are not convinced that we will not meet the estimated 1.0 percent outlay in outlier payments in CY 2008.

As discussed above in this section, we modeled the proposed fixed dollar threshold of $1,800 incorporating all proposed CY 2009 OPPS payment policies using CY 2007 claims, our best available charge and cost inflation assumptions, and CY 2008 CCRs. Because our estimates account for anticipated inflation in both charges and costs, we generally expect our threshold to increase each year. We would not retain the threshold at $1,575 because we believe this threshold would lead us to pay more than 1.0 percent of total estimated OPPS payment in outlier payments for CY 2009. The proposed fixed-dollar threshold also reflected any proposed changes in packaging for CY 2009. Because packaging also is considered in the cost estimation portion of the outlier eligibility and payment calculations, any proposed increase in packaging policy would not automatically lead to less outlier payments as one commenter suggested. This is because the costs of packaged items are distributed among the items and services eligible for outliers, increasing the likelihood that those eligible items and services would receive outlier payments.

We believe that our proposed methodology uses the best information we have at this time to yield the most accurate prospective fixed-dollar outlier threshold for the CY 2009 OPPS. The hospital multiple and fixed-dollar outlier thresholds are important parts of a prospective payment system and

should be based on projected payments using the latest available historical data, without adjustments for prior year actual expenditures. We do not adjust the prospective threshold for prior year differences in actual expenditure of outlier payments.

We do not believe it would be appropriate to increase the payment percentage to 80 percent of the difference between the APC payment and the cost of the services in order to align it with the IPPS outlier policy. In a budget neutral system with a specified amount dedicated to outlier payments, the payment percentage and fixed-dollar threshold are related. Raising the payment percentage would require us to significantly increase the fixed-dollar threshold to ensure that the estimated CY 2009 OPPS payments would not exceed the amount dedicated to outlier payments. The payment percentage also reflects the general level of financial risk. The 50 percent payment percentage under the OPPS corresponds to the lower financial risk presented by the OPPS cases compared to the IPPS, which largely makes a single payment for a complete episode-of-care.

Comment: One commenter supported the proposal to make brachytherapy sources eligible for outlier payments.

Response: In the CY 2009 OPPS/ASC proposed rule (73 FR 41502), we proposed prospective payment based on median costs for brachytherapy sources and proposed to assign brachytherapy sources to status indicator ''U.'' Subsequent to the issuance of the CY 2009 OPPS/ASC proposed rule, Congress enacted Public Law 110–275, which further extended the payment period for brachytherapy sources based on a hospital's charges adjusted to cost through CY 2009. In receiving payment at charges adjusted to cost, the outlier policy would no longer apply to brachytherapy sources because outlier eligibility and payment are calculated based on the difference between APC payment and estimated cost. Outlier payments are designed to buffer losses when hospital costs greatly exceed prospective payments. When section 142 of Public Law 110–275 once again continued payment for brachytherapy sources at charges adjusted to cost for CY 2009, we revisited § 419.43(f) of our regulations. Under § 419.43(f) of the regulations, we exclude certain items and services from qualification for outlier payments. We note that our longstanding policy has been that an item or service paid at charges adjusted to cost by a hospital-specific CCR is ineligible for outlier payments. This amendment does not alter our longstanding and consistent policy regarding the exclusion of drugs and biologicals that are assigned to separate APCs and items that are paid at charges adjusted to cost by application of a hospital-specific CCR. An item or service paid at charges adjusted to cost does not qualify for an outlier payment because the outlier eligibility calculation is based on the difference between APC payment and cost, where cost is estimated at charges adjusted to cost. When the APC payment for items is made at charges adjusted to cost, there is no difference between the APC payment and estimated cost and thus no outlier payment can be triggered. We believed it was administratively simpler to amend § 419.43(f) to exclude in a general manner items or services paid at charges adjusted to cost by application of a hospital-specific CCR from eligibility for an outlier payment, consistent with our historical policy, rather than amending the regulations to specifically cite each item or service that is excluded from an outlier payment because it is paid at charges adjusted to costs, currently brachytherapy sources and pass-through devices. Consequently, we are making a conforming technical amendment to § 419.43(f) to specify that items and services paid at charges adjusted to cost by application of a hospital-specific CCR are excluded from qualification for the payment adjustment under paragraph (d)(1) of this section [419.43].

In addition, we note that the estimated cost of pass-through devices will continue to be used in outlier payment and eligibility calculations as specified in § 419.43(d)(1)(i)(B). Specifically, this regulation text codifies the statutory provision of 1833(t)(5)(A)(i)(II) of the Act which requires that estimated payment for transitional pass-through devices be added to the APC payment amount for the associated procedure when determining outlier eligibility for the associated surgical procedure. However, we are making a technical correction to § 419.43(d)(1)(i)(B) to appropriately reference § 419.66. While § 419.43(d)(1)(i)(B) discusses the use of the pass-through payment in determining outlier eligibility, it currently incorrectly references paragraph (e) which discusses budget neutrality, instead of § 419.66 which sets for the specific rules on pass-through payments for devices. Thus, we are deleting the reference to the phrase ''paragraph (e) of this section'' and in its place substituting the correct cite ''§ 419.66.'' Pass-through devices are paid at charges adjusted to cost, and thus are not eligible to receive outlier payments on their own.

After consideration of the public comments received, we are finalizing our CY 2009 proposal for the outlier calculation, without modification, as outlined below.

3. Final Outlier Calculation

For CY 2009, we are applying the overall CCRs from the July 2008 OPSF file with a CCR adjustment factor of 0.9920 to approximate CY 2009 CCRs to charges on the final CY 2007 claims that were adjusted to approximate CY 2009 charges (using the final charge inflation factor of 1.1204). These are the same CCR adjustment and charge inflation factors that we used to set the IPPS fixed-dollar threshold for FY 2009 (73 FR 48763). We simulated the estimated aggregate CY 2009 outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiple 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 estimated total outlier payments equaled 1.0 percent of aggregated estimated total CY 2009 payments. We estimate that a fixed-dollar threshold of $1,800, combined with the multiple threshold of 1.75 times the APC payment rate, will allocate 1.0 percent of estimated aggregated total CY 2009 OPPS payments to outlier payments.

In summary, for CY 2009 we will continue to make an outlier payment that equals 50 percent of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment amount when both the 1.75 multiple threshold and the fixed-dollar $1,800 threshold are met. For CMHCs, if a CMHC provider's cost for partial hospitalization exceeds 3.40 times the APC payment rate, the outlier payment is calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC payment rate. We estimate that this threshold will allocate 0.12 percent of outlier payments to CMHCs for PHP outlier payments.

4. Outlier Reconciliation

As provided in section 1833(t)(5) of the Act, and described in the CY 2001 OPPS final rule with comment period (65 FR 18498), we initiated the use of a provider-specific overall CCR to estimate a hospital's or CMHC's costs from billed charges on a claim to determine whether a service's cost was significantly higher than the APC payment to qualify for outlier payment. Currently, these facility-specific overall

CCRs are determined using the most recent settled or tentatively settled cost report for each facility. At the end of the cost reporting period, the hospital or CMHC submits a cost report to its Medicare contractor, who then calculates the overall CCR that is used to determine prospective outlier payments for the facility. We believe the intent of the statute is that outlier payments would be made only in situations where the cost of a service provided is extraordinarily high. For example, under our existing outlier methodology, a hospital's billed current charges may be significantly higher than the charges included in the hospital's overall CCR that is used to calculate outlier payments, while the hospital's costs are more similar to the costs included in the overall CCR. In this case, the hospital's overall CCR used to calculate outlier payments is not representative of the hospital's current charge structure. The overall CCR applied to the hospital's billed charges would estimate an inappropriately high cost for the service, resulting in inappropriately high outlier payments. This is contrary to the goal of outlier payments, which are intended to reduce the hospital's financial risk associated with services that have especially high costs. The reverse could be true as well, if a hospital significantly lowered its current billed charges in relationship to its costs, which would result in inappropriately low outlier payments.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41463), for CY 2009, we proposed to address vulnerabilities in the OPPS outlier payment system that lead to differences between billed charges and charges included in the overall CCR used to estimate cost. Our proposal would apply to all hospitals and CMHCs paid under the OPPS. The main vulnerability in the OPPS outlier payment system is the time lag between the CCRs that are based on the latest settled cost report and current charges that creates the potential for hospitals and CMHCs to set their own charges to exploit the delay in calculating new CCRs. A facility can increase its outlier payments during this time lag by increasing its charges significantly in relation to its cost increases. The time lag may lead to inappropriately high CCRs relative to billed charges that overestimate cost, and as a result, greater outlier payments. Therefore, we proposed to take steps to ensure that outlier payments appropriately account for financial risk when providing an extraordinarily costly and complex service, while only being made for services that legitimately qualify for the additional payment.

We believe that some CMHCs may have historically increased and decreased their charges in response to Medicare outlier payment policies. The HHS Office of the Inspector General (OIG) has published several reports that found that CMHCs took advantage of vulnerabilities in the outpatient outlier payment methodology by increasing their billed charges after their CCRs were established to garner greater outlier payments (DHHS OIG June 2007, A–07–06–0459, page 2). We discuss the OIG's most recent report and accompanying recommendations in section XIV.C. of this final rule with comment period. We similarly noted in the CY 2004 OPPS final rule with comment period (68 FR 63470) that some CMHCs manipulated their charges in order to inappropriately receive outlier payments.

To address these vulnerabilities in the area of the OPPS outlier payment methodology, we proposed to update our regulations to codify two existing longstanding OPPS policies related to CCRs, as discussed in further detail below in this section. In addition to codifying two longstanding policies related to CCRs, we also proposed a new provision giving CMS the ability to specify an alternative CCR and allowing hospitals to request a new CCR based on substantial evidence. Finally, we proposed to incorporate outlier policies comparable to those that have been included in several Medicare prospective payment systems, in particular the IPPS (68 FR 34494). Specifically, we proposed to require reconciliation of outlier payments in certain circumstances. We stated our belief that these proposed changes would address most of the current vulnerabilities present in the OPPS outlier payment system.

First, we proposed to update the regulations to codify two existing outlier policies (73 FR 41463). These policies are currently stated in Pub 100–04, Chapter 4, section 10.11.1 of the Internet-Only Manual, as updated via Transmittal 1445, Change Request 5946, dated February 8, 2008. To be consistent with our manual instructions, for CY 2009, we proposed to revise 42 CFR 419.43 to add two new paragraphs (d)(5)(ii) and (d)(5)(iii). Specifically, we proposed to add new paragraph (d)(5)(ii) to incorporate rules governing the overall ancillary CCR applied to processed claims and new paragraph (d)(5)(iii) to incorporate existing policy governing when a statewide average CCR may be used instead of an overall ancillary CCR. We note that use of a statewide average CCR in the specified cases is to ensure that the most appropriate CCR possible is used for outlier payment calculations. For purposes of this discussion and OPPS payment policy in general, we treat ''overall CCR'' and ''overall ancillary CCR'' as synonymous terms that refer to the overall CCR that is calculated based on cost report data, which for hospitals, pertains to a specific set of ancillary cost centers.

We proposed new § 419.43(d)(5)(ii) to specify use of the hospital's or CMHC's most recently updated overall CCR for purposes of calculating outlier payments. Our ability to identify true outlier cases depends on the accuracy of the CCRs. To the extent some facilities may be motivated to maximize outlier payments by taking advantage of the time lag in updating the CCRs, the payment system remains vulnerable to overpayments to individual hospitals or CMHCs. This proposed provision specified that the overall CCR applied at the time a claim is processed is based on either the most recently settled or tentatively settled cost report, whichever is from the latest cost reporting period. We also proposed new § 419.43(d)(5)(iii) to describe several circumstances in which a Medicare contractor may substitute a statewide average CCR for a hospital's or CMHC's CCR. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68006), we finalized this policy but inadvertently did not update our regulations. We refer readers to section II.D. of this final rule with comment period for a more detailed discussion of statewide average CCRs. In summary, Medicare contractors can use a statewide CCR for new hospitals or CMHCs that have not accepted assignment of the existing provider agreement and who have not yet submitted a cost report; for hospitals or CMHCs whose Medicare contractor is unable to obtain accurate data with which to calculate the overall ancillary CCR; and for facilities whose actual CCR is more than 3 standard deviations above the geometric mean of other overall CCRs. For CY 2009, we estimate this upper threshold to be 1.3. While this existing policy minimizes the use of CCRs that are significantly above the mean for cost estimation, facilities with CCRs that fall significantly below the mean would continue to have their actual CCRs utilized, instead of the statewide default CCR. We also proposed to reevaluate the upper threshold and propose a new upper threshold, if appropriate, through rulemaking each year.

These improvements would somewhat mitigate, but would not fully eliminate, a hospital's or CMHC's ability to significantly increase its charges in relation to its cost increases each year, thereby receiving significant outlier payments because of the inflated CCR. Therefore, we also proposed two new policies to more fully address the vulnerabilities described above. Specifically, we proposed new § 419.43(d)(5)(i) that stated that for hospital outpatient services performed on or after January 1, 2009, CMS may specify an alternative CCR or the facility may request an alternative CCR under certain circumstances. The alternative CCR in either case may be either higher or lower than the otherwise applicable CCR. In addition, we proposed to allow a facility to request that its CCR be prospectively adjusted if the facility presents substantial evidence that the overall CCR that is currently used to calculate outlier payments is inaccurate. Such an alternative CCR may be appropriate if a facility's charges have increased at an excessive rate, relative to the rate of increase among other hospitals or CMHCs. CMS would have the authority to direct the Medicare contractor to calculate a CCR from the cost report that accounts for the increased charges. As explained in greater detail below in this section, we also proposed new § 419.43(d)(5)(iv), now (d)(6), to allow Medicare contractors the administrative discretion to reconcile hospital or CMHC cost reports under certain circumstances.

We also proposed to implement a reconciliation process similar to that implemented by the IPPS in FY 2003 (68 FR 34494). This proposed policy would subject certain outlier payments to reconciliation when a hospital or CMHC cost report is settled. While the existing policies described above in this section partially address the vulnerabilities in the OPPS outlier payment system, the proposed reconciliation process would more fully ensure accurate outlier payments for those facilities whose CCRs fluctuate significantly, relative to the CCRs of other facilities. We proposed that this reconciliation process would only apply to those services provided on or after January 1, 2009 (73 FR 41464). We considered proposing that this reconciliation process would become effective beginning with services provided during the hospital's first cost reporting period beginning in CY 2009 but believed effectuating this policy based upon date of service could be less burdensome for hospitals. We specifically solicited public comment related to the effective date for the reconciliation process that would be most administratively feasible for hospitals and CMHCs. We noted this reconciliation process would be done on a limited basis in order to ease the administrative burden on Medicare contractors, as well as to focus on those facilities that appear to have improperly manipulated their charges to receive excessive outlier payments. We proposed to set reconciliation thresholds in the manual, reevaluate them annually, and modify them as necessary. Following current IPPS outlier policy, these thresholds would include a measure of acceptable percent change in a hospital's or CMHC's CCR and an amount of outlier payment involved. We further proposed that when the cost report is settled, reconciliation of outlier payments would be based on the overall CCR calculated based on the ratio of costs and charges computed from the cost report at the time the cost report coinciding with the service dates is settled. Reconciling these outlier payments would ensure that the outlier payments made are appropriate and that final outlier payments would reflect the most accurate cost data. We did not propose to apply reconciliation to services and items not otherwise subject to outlier payments, including items and services paid at charges adjusted to cost (73 FR 41464).

This reconciliation process would require recalculating outlier payments for individual claims. We understand that the aggregate change in a facility's outlier payments cannot be determined because changes in the CCR would affect the eligibility and amount of outlier payment. For example, if a CCR declined, some services may no longer qualify for any outlier payments while other services may qualify for lower outlier payments. Therefore, the only way to accurately determine the net effect of a decrease in an overall CCR on a facility's total outlier payments is to assess the impact on a claim-by-claim basis. At this time, CMS is developing a method for reexamining claims to calculate the change in total outlier payments for a cost reporting period using a revised CCR.

Similar to the IPPS, we also proposed to adjust the amount of final outlier payments determined during reconciliation for the time value of money (73 FR 41464). A second vulnerability remaining after reconciliation is related to the same issue of the ability of hospitals and CMHCs to manipulate the system by significantly increasing charges in the year the service is performed, and obtaining excessive outlier payments as a result. Even though under the proposal the excess money would be refunded at the time of reconciliation, the facility would have access to excess payments from the Medicare Trust Fund on a short-term basis. In cases of underpayment, the facility would not have had access to appropriate outlier payment for that time period.

Accordingly, we believed it would be necessary to adjust the amount of the final outlier payment to reflect the time value of the funds for that time period. Therefore, we proposed to add section § 419.43(d)(6) to provide that when the cost report is settled, outlier payments would be subject to an adjustment to account for the value of the money for the time period in which the money was inappropriately held by the hospital or CMHC (73 FR 41464 through 41465). This would also apply where outlier payments were underpaid. In those cases, the adjustment would result in additional payments to hospitals or CMHCs. Any adjustment would be made based on a widely available index to be established in advance by the Secretary, and would be applied from the midpoint of the cost reporting period to the date of reconciliation (or when additional payments are issued, in the case of underpayments). This adjustment to reflect the time value of a facility's outlier payments would ensure that the outlier payment finalized at the time its cost report is settled appropriately reflected the hospital's or CMHC's approximate marginal costs in excess of the APC payments for services, taking into consideration the applicable outlier thresholds.

Despite the fact that each individual facility's outlier payments may be subject to adjustment when the cost report is settled, we noted our continued belief that the hospital multiple and fixed-dollar outlier thresholds should be based on projected payments using the latest available historical data, without retroactive adjustments, to ensure that actual outlier payments are equal to the target spending percentage of total anticipated hospital outpatient spending. The proposed reconciliation process and ability to change overall CCRs would be intended only to adjust actual outlier payments so that they most closely reflected true costs rather than artificially inflated costs. These adjustments would be made irrespective of whether total outlier spending targets were met or not.

In the CY 2009 OPP/ASC proposed rule (73 FR 41465), we did not propose to make any changes to the method that

we use to calculate outlier thresholds for CY 2009. The multiple and fixed-dollar outlier thresholds are an important aspect of the prospective nature of the OPPS and key to their importance is their predictability and stability for the prospective payment year. The outlier payment policy is designed to alleviate any financial disincentive hospitals may have to providing any medically necessary care their patients may require, even to those patients who are very sick and would be likely more costly to treat. Preset and publicized OPPS outlier thresholds allow hospitals and CMHCs to approximate their Medicare payment for an individual patient while that patient is still in the hospital. Even though we proposed to make outlier payments susceptible to a reconciliation based on the facility's actual CCRs during the contemporaneous cost reporting period, the facility should still be in a position to make this approximation. Hospitals and CMHCs have immediate access to the information needed to determine what their CCR will be for a specific time period when their cost report is settled. Even if the final CCR is likely to be different from the ratio used initially to process and pay the claim, hospitals and CMHCs not only have the information available to estimate their CCRs, but they also have the ability to control those CCRs, through the structure and levels of their charges. If we were to make retroactive adjustments to hospital outlier payments to ensure that we met total OPPS outlier spending targets, we would undermine the critical predictability aspect of the prospective nature of the OPPS. Making such an across-the-board adjustment would lead to either more or less outlier payments for all hospitals that would, therefore, be unable to immediately approximate the payment they would receive for especially costly services at the time those services were provided. We continue to believe that it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment.

Comment: Some commenters were opposed to outlier reconciliation because they believed that the concept of reconciliation is contrary to the nature of a prospective payment system. One commenter asserted that the proposed reconciliation process would be administratively burdensome to hospitals due to the volume of outpatient encounters and number of claims involved. Another commenter believed that hospitals, which typically increase charges at the beginning of each fiscal year, should not have to be held to a prior period CCR for settlement purposes. One commenter suggested that the impact of the outlier reconciliation be identified, and should the impact grow too large, that it be included in the development of the outlier thresholds. Another commenter sought alternatives to the reconciliation process and suggested controlling outlier payments through the percentage of payments set aside for outlier payments, as well as more timely settlement of cost reports to avoid the need for reconciliation. Several commenters suggested waiting until the newly revised cost reporting forms are in place before implementing the outlier reconciliation proposal in order to assess changes to the CCRs and potentially use more accurate CCRs for outlier payment.

Many commenters recommended that the effective date for implementation of the outlier reconciliation policy be the first cost reporting period in CY 2009. Several commenters sought further clarification regarding the expected outlier reconciliation thresholds, as well as the reasoning behind their development. Some commenters believed that the OPPS reconciliation policy should implement the same outlier reconciliation thresholds as the IPPS, or should use them as a guide in developing OPPS-specific thresholds. A few commenters recommended that the CCR fluctuation threshold should be the same as in the IPPS because the same data from the cost report would be used in both cases. Many commenters believed that the outlier reconciliation policy should be applied on a limited basis.

Response: According to commenters, the concept of reconciliation is contrary to the idea of a prospective payment system. We believe it is contrary to the concept of a prospective payment system for hospitals to be able to increase outlier payments by manipulating their charges for the current year. We believe that reconciliation would help address this vulnerability in outlier payment, without affecting the overall prospective nature of the OPPS. Any action regarding reconciling the outlier payments of an individual hospital would not affect the predictability of the system because we are not proposing to make any adjustments to the prospectively set outlier multiple and fixed-dollar thresholds and payment methodology. We will continue to use the best data available to set the annual OPPS outlier thresholds. Hospitals would continue to be capable of calculating any outlier payments they would receive, using information that is readily available to them through their accounting systems. While we are finalizing the proposed outlier reconciliation policy, as described above, we are not making retroactive adjustments to our outlier threshold to meet a dedicated percentage of total payments set aside for outlier payments. This approach maintains the prospective nature of the OPPS outlier payment and will enable hospitals to approximate their outlier payments and potential eligibility for reconciliation.

In section II.A.1.c. of this final rule with comment period, we indicate that we are updating the Medicare hospital cost report form and that we plan to publish this form for public comment. It is possible that the new cost report form could lead to more accurate overall CCRs. Although some commenters suggested that we postpone the implementation of the outlier reconciliation policy until the revised cost report form is available to capitalize on this potential for improved accuracy, we do not believe that minor improvements in the accuracy of the overall CCR, a gross measure, warrant delaying outlier reconciliation. In order to determine an effective date for the policy that would minimize the administrative burden of the outlier reconciliation process, we specifically solicited public comment regarding the effective implementation date of this policy. We have considered the comments regarding the effective implementation date of the outlier reconciliation process and believe that the first cost reporting period of CY 2009 would be the most appropriate start date. Therefore, we expect that for hospital outpatient services furnished during the cost reporting periods beginning on or after January 1, 2009, that if the hospital qualifies for reconciliation, the amount of outlier payments will be recalculated using the actual CCR computed from the relevant cost report and claims data for each service furnished during the cost reporting period and that any difference in aggregate outlier payment, adjusted for the time value of money, will be handled at cost report settlement.

While we recognize the burden involved in potentially subjecting hospitals to an outlier reconciliation process, we believe that appropriate outlier reconciliation thresholds will ensure that the limited resources of Medicare contractors are focused upon those hospitals that appear to have disproportionately benefited from the time lag in updating their CCRs. We intend to issue manual instructions in the near future to assist Medicare

contractors in implementing the outlier reconciliation provision for CY 2009. In those manual instructions, we will issue thresholds for Medicare contractors to use to determine when a hospital or CMHC will qualify for reconciliation for the first cost reporting period beginning on or after January 1, 2009.

We recognize the commenters' concerns regarding the reconciliation thresholds that we would set to focus on those hospitals whose charging structures fluctuate significantly. In considering reconciliation thresholds for the OPPS, we have used the existing IPPS thresholds as a guide in identifying hospitals in which outlier reconciliation would be appropriate. For cost reports beginning in CY 2009, we are considering instructing Medicare contractors to conduct reconciliation for hospitals and CMHCs whose actual CCRs at the time of cost report settlement are found to be plus or minus 10 percentage points from the CCR used during the cost reporting period to make outlier payments, and for hospitals that have total OPPS outlier payments that exceed $200,000. The change in CCR threshold would be the same threshold used under the IPPS. We are still considering whether to adopt an outlier payment threshold specifically for CMHCs. The hospital outlier payment threshold of $200,000 serves the same purpose as the IPPS $500,000 threshold, but is proportional to OPPS outlier payments. We estimate that the $200,000 threshold would identify roughly the same number of hospitals as the IPPS threshold of $500,000. We believe that these thresholds would appropriately identify hospitals receiving outlier payments that are substantially different from the ones indicated by their actual costs and charges, while ensuring limited application of the outlier reconciliation policy. Hospitals exceeding these thresholds during their applicable cost reporting periods would become subject to reconciliation of their outlier payments. These thresholds would be reevaluated annually and, if necessary, modified each year in order to ensure that reconciliation is performed on a limited basis and focused on those hospitals that appear to have disproportionately benefited from the outlier payment vulnerabilities. As under the IPPS, we also retain the discretion to recommend other hospitals' cost reports for reconciliation.

As under the IPPS, we did not propose to adjust the fixed-dollar threshold or amount of total OPPS payment set aside for outlier payments for reconciliation activity. As noted above in this section, the predictability of the fixed-dollar threshold is an important component of a prospective payment system. We would not adjust the prospectively set threshold for the amount of payment reconciled at cost report settlement. Our outlier threshold calculation assumes that CCRs accurately estimate hospital costs based on information available to us at the time we set the prospective fixed-dollar outlier threshold. For these reasons, we are not making any assumptions about the effects of reconciliation on the outlier threshold calculation.

With regard to other suggested alternatives to an outlier reconciliation process, we note that more timely cost report settlement would not address the fundamental vulnerability in using a prior period CCR to project cost in the prospective payment year. While timely cost report settlement is valuable, significant differences might still exist between the actual CCR and the one used to estimate cost in the outlier payment calculation. We also clarify that hospitals would not be held to a prior period CCR for settlement. The reconciliation process will ensure that CMS uses an actual year CCR for cost report settlement when outlier payments are significant and may not have been accurate.

Comment: Some commenters supported the proposal to substitute CCRs based on the most recent cost report or other alternate CCRs where appropriate. Several commenters recommended changes to the regulation text that would more specifically delineate the situations in which CMS could specify an alternative CCR, believing that the proposed regulation text placed no limits on the circumstances in which an alternative CCR could be applied. Some commenters requested that CMS automatically notify a provider if its CCR is three standard deviations below the geometric mean and potentially replace those CCRs with a statewide CCR. They believed that this would protect the Medicare program against CCR manipulation and do more to correct both ''underpayments'' and ''overpayments'' of outliers as they occur.

Response: Although we recognize the commenters' concern regarding situations in which CMS could direct Medicare contractors to use an alternative CCR, we believe we must retain the flexibility to quickly respond should we uncover excessive discrepancies between anticipated actual CCRs and the ones being used to estimate costs for outlier payments. This could entail observation of significant increases in a hospital's or CMHC's charges over a short period of time, potentially to garner greater outlier payments, but also could occur if a hospital accepted assignment in a change of ownership and needed CMS to quickly change the CCR being used for payment in order to help the new owners avoid reconciliation. We believe that limiting the circumstances in which CMS could specify an alternative CCR would limit our ability to respond quickly. We do not anticipate using that authority frequently. It likely would be isolated to situations where immediate action would be necessary.

Some commenters requested that a statewide CCR be used as a substitute in situations where CCRs fall three standard deviations below the geometric mean, similar to the policy for excessively high CCRs. We believe that the CCR of hospitals who have CCRs that fall below three standard deviations below the geometric mean is an accurate reflection of the relationship between their costs and charges. Implementing a statewide floor would provide an incentive for hospitals to take advantage of the policy by manipulating their charging structures so that their hospital-specific CCR would be replaced by a statewide CCR. We have previous experience under the IPPS outlier policy with hospitals increasing their charges significantly in order to lower their CCRs, resulting in assignment of the statewide average. This manipulation would allow hospitals to reach a higher estimation of cost than actually exists. No similar incentive exists for hospitals to increase their CCRS to the ceiling. In the FY 2004 IPPS final rule (68 FR 34500), we removed the IPPS requirement that hospitals with a CCR below the floor be assigned the statewide average and we have adopted the same policy in manual instructions for the OPPS, as noted above. For CY 2009, we estimate the upper threshold at which we would substitute to the statewide CCR for a hospital's CCR to be 1.3.

Comment: One commenter supported the time value of money adjustment which would be included in situations where outlier reconciliation applied. Other commenters did not support the time value of money adjustment because of the recent experience under the IPPS. The IPPS is still finalizing the technical methodology for conducting accurate reconciliation and the commenters did not want to be penalized for holding outlier overpayments while waiting for reconciliation. One commenter argued against the time value of money adjustment because the commenter believed there was insufficient information about how the calculation

would be conducted. A commenter believed that interest should only be accrued if a provider did not pay in a timely manner the amount due to Medicare after being issued a Notice of Program Reimbursement at cost report settlement.

Response: The time value of money adjustment was proposed to address the outlier payment vulnerability that would remain even after a cost report reconciliation policy was in place. Outlier payments are uniquely susceptible to manipulation because hospitals set their own charging structure and can change it during a cost reporting period without the Medicare contractor's knowledge. By manipulating its CCRs, a hospital could inappropriately gain excess payments from the Medicare Trust Fund on a short-term basis. We believe that the current IPPS situation, where hospitals must wait to reconcile cost reports until CMS can operationally refine the system of IPPS outlier reconciliation, is unique and that adjustment for the time value of money makes sense for long-term implementation. Furthermore, the provision offers hospitals the same interest adjustment should CMS owe hospitals additional outlier payments. We specify the time value of money calculation in the Medicare Claims Processing Manual, Pub 100–04, Chapter 3, Section 20.1.2.7. For the OPPS, we intend to employ the same calculation, and we will use the same index, which is the monthly rate of return that the Medicare Trust Fund earns.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, with modification, for an OPPS outlier reconciliation policy. We are implementing the outlier reconciliation policy for each hospital and CMHC for services furnished during cost reporting periods beginning in CY 2009, and we are including an adjustment for the time value of money. We have modified § 419.43(d)(6) to reflect this change to the effective date. We also reorganized the provisions of § 419.43(d)(5) and § 419.43(d)(6) to better separate the concept of CCRs and outlier reconciliation processes. In reviewing our proposed regulation text for outlier reconciliation, we noted that use of ''Reconciliation'' was not the appropriate title for § 419.43(d)(5), which included both CCRs and the reconciliation process itself. We have modified our regulation text to separately identify the concepts of CCRs and reconciliation and have labeled § 419.43(d)(5) as ''Cost-to-Charge Ratios for Calculating Charges Adjusted to Cost'' and § 419.43(d)(6) as ''Reconciliation.''

G. 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 §§ 419.31, 419.32, 419.43 and 419.44. The payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this final rule with comment period and the relative weight determined under section II.A. of this final rule with comment period. Therefore, the national unadjusted payment rate for most APCs contained in Addendum A to this final rule with comment period and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this final rule with comment period was calculated by multiplying the final CY 2009 scaled weight for the APC by the final CY 2009 conversion factor. We note that 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 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 XVI.D. of this final rule with comment period.

We demonstrate in the steps below how to determine the APC payment that will 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,'' ''V,'' or ''X'' (as defined in Addendum D1 to this final rule with comment period), in a circumstance in which the multiple procedure discount does not apply and the procedure is not bilateral. We note that, as discussed in section VII.B. of this final rule with comment period, brachytherapy sources, to which we proposed assigning status indicator ''U'' for CY 2009, are required by section 142 of Public Law 110–275 to be paid on the basis of a hospital's charges adjusted to cost. Therefore, these items are not subject to the annual OPPS payment update factor and, therefore, will not be subject to the CY 2009 payment reduction for a hospital's failure to meet the HOP QDRP requirements.

Individual providers interested in calculating the payment amount that they specifically will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this final rule with comment period 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 0.981 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 2009 OPPS increase factor.

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

x—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 new geographic statistical areas as a result of revised OMB standards (urban and rural) to which hospitals are assigned for FY 2009 under the IPPS, reclassifications through the MGCRB, section 1886(d)(8)(B) ''Lugar'' hospitals, and section 401 of Public Law 108–173. In the CY 2009 OPPS/ASC proposed rule (73 FR 41466), we noted that the reclassifications of hospitals under section 508 of Public Law 108–173 were scheduled to expire on September 30, 2008 and would not be applicable to FY 2009 and, therefore, would not apply to the CY 2009 OPPS. However, section 124 of Public Law 110–275 extended these reclassifications and special exception wage indices through September 30, 2009. For further discussion of the changes to the FY 2009 IPPS wage index, as applied to the CY 2009 OPPS, we refer readers to section II.C. of this final rule with comment period. The wage index values include the occupational mix adjustment described in section II.C. of this final rule with comment period that was developed for the final FY 2009 IPPS payment rates published in the **Federal Register** on August 19, 2008 (73 FR 48778) and finalized in a subsequent document published in the **Federal Register** on October 3, 2008 (73 FR 57888 through 58017).

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of Public Law 108–173. Addendum L to this final rule with comment period contains the qualifying counties and the final wage index increase developed for the FY 2009 IPPS published in the FY 2009 IPPS final rule as Table 4J (73 FR 48883 through 48898) and finalized in a subsequent document published in the **Federal Register** on October 3, 2008 (73 FR 57988). This step is to be followed only if the hospital has chosen not to accept reclassification under Step 2 above.

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—Labor-related portion of the national unadjusted payment rate (wage adjusted)

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

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

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

y—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, as defined 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 full and reduced national unadjusted payment rates that will apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the HOP QDRP requirements, using the steps outlined above. For purposes of this example, we will 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 CY 2009 full national unadjusted payment rate for APC 0019 is $295.69. The reduced national unadjusted payment rate for a hospital that fails to meet the HOP QDRP requirements is $290.07. This reduced rate is calculated by multiplying the reporting ratio of 0.981 by the full unadjusted payment rate for APC 0019.

The FY 2009 wage index for a provider located in CBSA 35644 in New York is 1.2996. The labor portion of the full national unadjusted payment is $230.56 (.60 * $295.69 * 1.2996). The labor portion of the reduced national unadjusted payment is $226.18 (.60 * $290.07 * 1.2996). The nonlabor portion of the full national unadjusted payment is $118.27 (.40 * $295.69). The nonlabor portion of the reduced national unadjusted payment is $116.02 (.40 * $290.07). The sum of the labor and nonlabor portions of the full national adjusted payment is $348.83 ($230.56 + $118.27). The sum of the reduced national adjusted payment is $342.20 ($226.18 + $116.02).

We did not receive any public comments concerning our proposed methodology for calculating an adjusted payment from the national unadjusted Medicare payment amount for CY 2009. Therefore, we are finalizing our proposed CY 2009 methodology, without modification.

H. Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining 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 2009, 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. Sections 1834(d)(2)(C)(ii) and (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.

2. Copayment Policy

For CY 2009, we proposed to determine copayment amounts for new

and revised APCs using the same methodology that we implemented for CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period (68 FR 63458)). In addition, we proposed to use the same rounding methodology implemented in CY 2008 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).) The national unadjusted copayment amounts for services payable under the OPPS that will be effective January 1, 2009, are shown in Addenda A and B to this final rule with comment period. As discussed in section XVI.D. of this final rule with comment period, we are finalizing our proposal for CY 2009 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 equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We did not receive any public comments regarding this proposal. Therefore, we are finalizing our CY 2009 proposal for determining APC copayment amounts, without modification.

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

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its 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, $71.87 is 24.306 percent of the full national unadjusted payment rate of $295.69.

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—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 section II.G. of this final rule with comment period. Calculate the rural adjustment for eligible providers as indicated in section II.G. of this final rule with comment period.

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

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

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

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

Step 4. For a hospital that failed to meet its HOP QDRP requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.981.

The unadjusted copayments for services payable under the OPPS that will be effective January 1, 2009, are shown in Addenda A and B to this final rule with comment period. We note that the national unadjusted payment rates and copayment rates shown in Addenda A and B to this final rule with comment period reflect the full market basket conversion factor increase, as discussed in section XVI.D. of this final rule with comment period.

III. OPPS Ambulatory Payment Classification (APC) Group Policies

A. OPPS Treatment of New HCPCS and CPT Codes

1. Treatment of New HCPCS Codes Included in the April and July Quarterly OPPS Updates for CY 2008

During the April and July quarters of CY 2008, we created a total of 11 new Level II HCPCS codes that were not addressed in the CY 2008 OPPS/ASC final rule with comment period that updated the CY 2008 OPPS. For the April quarter of CY 2008, we recognized for separate payment a total of four new Level II HCPCS codes, specifically C9241 (Injection, doripenem, 10 mg); Q4096 (Injection, von willebrand factor complex, human, ristocetin cofactor (not otherwise specified), per i.u. VWF:RCO); Q4097 (Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg); and Q4098 (Injection, iron dextran, 50 mg). For the July quarter of CY 2008, we recognized a total of seven new Level II HCPCS codes, specifically C9242 (Injection, fosaprepitant, 1 mg); C9356 (Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter); C9357 (Dermal substitute, granulated cross-linked collagen and glycosaminoglycan matrix (Flowable Wound Matrix), 1 cc); C9358 (Dermal substitute, native, non-denatured collagen (SurgiMend Collagen Matrix), per 0.5 square centimeters); G0398 (Home sleep study test (HST) w/type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation); G0399 (Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation); and G0400 (Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels). We designated the payment status of these codes and added them either through the April update (Transmittal 1487, Change Request 5999, dated April 8, 2008) or the July update (Transmittal 1536, Change Request 6094, dated June 19, 2008) of the CY 2008 OPPS.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41467), we also solicited public comment on the status indicators, APC assignments, and payment rates of these codes, which were listed in Table 10 and Table 11 of that proposed rule and now appear in Tables 12 and 13, respectively, of this final rule with comment period. Because of the timing of the proposed rule, the codes implemented through the July 2008 OPPS update were not included in Addendum B to the proposed rule. We proposed to assign these new HCPCS codes for CY 2009 to APCs with the proposed payment rates as displayed in Table 11 and incorporate them into Addendum B to this final rule with comment period for CY 2009, which is consistent with our annual OPPS update policy. The HCPCS codes implemented through the April 2008 OPPS update and displayed in Table 10 were included in Addendum B to the proposed rule, where their proposed payment rates also were shown.

For CY 2009, the CMS HCPCS Workgroup created permanent HCPCS J-codes for four codes that were implemented in April 2008 and one code that was implemented in July 2008. Consistent with our general policy of using permanent HCPCS codes, if appropriate, rather than HCPCS C-codes

or Q-codes for the reporting of drugs under the OPPS in order to streamline coding, we display the new HCPCS J-codes in Tables 12 and 13 that replace the HCPCS C-codes or Q-codes, effective January 1, 2009. Specifically, J1267 (Injection, doripenem, 10 mg) replaces C9241; J7186 (Injection, antihemophilic factor viii/von willebrand factor complex (human), per factor viii i.u.) replaces Q4096; J1459 (Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg) replaces Q4097; J1750 (Injection, iron dextran, 50 mg) replaces Q4098; and J1453 (Injection, fosaprepitant, 1 mg) replaces C9242. The HCPCS J-codes describe the same drugs and the same dosages as the HCPCS C-codes and Q-codes that will be deleted, effective December 31, 2008. We note that HCPCS C-codes and Q-codes are temporary national HCPCS codes. To avoid duplication, temporary national HCPCS codes, such as C, G, K, and Q-codes, are generally deleted once permanent national HCPCS codes are created that describe the same item, service, or procedure. Because HCPCS codes J1267, J1453, and J1459 describe the same drugs and the same dosages that are currently designated by HCPCS codes C9241, C9242, and Q4097, respectively, we are continuing their pass-through status in CY 2009, and are assigning the HCPCS J-codes to the same APCs and status indicators as their predecessor HCPCS C-codes, as shown in Tables 12 and 13. Specifically, HCPCS code J1267 is assigned to the same APC (9241) and status indicator (''G'') as HCPCS code C9241, HCPCS code J1453 is assigned to the same APC (9242) and status indicator (''G'') as HCPCS code C9242, and HCPCS code J1459 is assigned to the same APC (1214) and status indicator (''G'') as HCPCS code Q4097.

In addition, new HCPCS code Q4114 (Allograft, Integra Flowable Wound Matrix, injectable, 1 cc) for January 1, 2009 replaces HCPCS code C9357. Because HCPCS code Q4114 describes the same biological and dosage descriptor as its predecessor HCPCS code, HCPCS code Q4114 is assigned the same status indicator as HCPCS code C9357 (''G'') and continues its pass-through status in CY 2009.

Except for the public comments that we received concerning the three new HCPCS G-codes for home sleep tests, we did not receive any public comments regarding the proposed APC and status indicator assignments for any of the other new HCPCS codes that were implemented in either April 2008 or July 2008. Therefore, for CY 2009, we are adopting as final the designated APCs for the replacement HCPCS J-codes, specifically J1267, J1453, J1459, J1750, and J7186, as well as HCPCS codes C9356, C9358, and Q4114, as shown in Tables 12 and 13 below, and in Addendum B to this final rule with comment period.

Comment: One commenter did not understand why the three home sleep testing HCPCS G-codes, that is G0398, G0399, and G0400, were recognized under the OPPS when it was the commenter's understanding that HCPCS G-codes are to be used only for physician billing. The commenter also requested clarification on the following issues: (1) The intended method for hospitals and independent diagnostic testing facilities (IDTFs) to bill for outpatient home sleep testing; (2) whether CMS will pay hospitals and IDTFs for home sleep testing that meets the criteria for CPT code 95806; (3) the relationship between CPT code 95806 (Sleep study, simultaneous recording of ventilation, respiratory effort, ecg or heart rate, and oxygen saturation, unattended by a technologist) and the new HCPCS G-codes, and how hospitals, IDTFs and physicians might properly code for a procedure that fulfills both descriptions; and (4) whether CMS will allow separate billing for the technical and professional components of this service by physicians and facilities.

Response: HCPCS G-codes are not limited to physician reporting. Since implementation of the OPPS in August 2000, Medicare has recognized HCPCS G-codes for reporting under the OPPS for hospital outpatient services. HCPCS G-codes are a subset of the Level II HCPCS codes and describe temporary procedures and services that are not described by any CPT codes. Created by CMS, this subset of codes is updated on a quarterly basis and may be reported by providers for any health insurers for various sites of services. While the codes may be used by any health insurers, it is up to the individual insurers to provide guidance on the reporting of these codes.

CMS created three new HCPCS G-codes, specifically G0398, G0399, and G0400, that were implemented on March 13, 2008, to describe the various types of home sleep tests that Medicare determined could be used to allow for coverage of continuous positive airway pressure (CPAP) therapy based upon a diagnosis of obstructive sleep apnea (OSA) according to a home sleep study. CMS reconsidered its 2005 NCD regarding CPAP therapy for OSA, effective March 13, 2008, to allow for coverage of CPAP therapy based on a diagnosis of OSA from a home sleep study. This NCD does not ensure coverage of sleep testing, but rather states when CPAP therapy is covered as a result of clinical evaluation and a positive sleep test.

The OPPS makes payment only to hospitals for their facility services, not to physicians or IDTFs. We proposed to assign these new HCPCS G-codes to APCs for payment under the OPPS because we believe these diagnostic services may be provided by HOPDs to Medicare beneficiaries. Because these new HCPCS G-codes specify home sleep studies and CPT code 95806 only refers to an unattended sleep study, hospitals providing home sleep studies should report the more specific HCPCS G-codes under these circumstances, according to the general coding principle that the most specific code should be reported for a service, unless CMS or Medicare contractors have provided other instructions.

Comment: One commenter expressed concern regarding the proposed payment rates for the three new HCPCS G-codes for home sleep studies. The commenter indicated that the proposed payment rate of approximately $153 for APC 0213 (Level I Extended EEG and Sleep Studies) to which these HCPCS codes were proposed for assignment is inappropriate. The commenter further stated that it appears that CMS's decision to use CPT code 95806 as the benchmark in setting the payment rates for these new HCPCS G-codes is flawed. The commenter asserted that CPT code 95806 was created in 1998 and is seldom reported and, therefore, does not appropriately reflect the current costs of providing home sleep testing. The commenter requested that CMS take into consideration the current cost of portable monitors, staff time, and administrative support associated with home sleep testing in determining the appropriate payment rate for these new services. The commenter suggested that the payment rate for HCPCS G-codes G0398, G0399, and G0400 should be about $550.

Response: Based on consultation with our medical advisors and on our review of the components of these services, we believe that home sleep testing is most appropriately assigned to APC 0213, as proposed. In determining the payment rates for HCPCS G-codes G0398, G0399, and G0400, we took into consideration the clinical and resource characteristics associated with providing home sleep testing. As has been our policy, we will analyze the hospital resource costs for home sleep testing in order to determine in the future whether proposals of alternative APC assignments may be warranted once we have hospital claims

data for these HCPCS G-codes. Since these codes were implemented in July 2008, the CY 2010 OPPS/ASC rulemaking cycle will be the first time that we will have cost data for these new HCPCS codes available for analysis.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to assign new HCPCS codes G0398, G0399, and G0400 to APC 0213, with a final CY 2009 APC median cost of approximately $150.

TABLE 12—NEW HCPCS CODES IMPLEMENTED IN APRIL 2008

CY 2008 HCPCS code	CY 2009 HCPCS code	CY 2009 long descriptor	Final CY 2009 status indicator	Final CY 2009 APC
C9241	J1267	Injection, doripenem, 10 mg	G	9241
Q4096	J7186	Injection, antihemophilic factor viii/von willebrand factor complex (human), per factor viii i.u.	K	1213
Q4097	J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg.	G	1214
Q4098	J1750	Injection, iron dextran, 50 mg	K	1237

TABLE 13—NEW HCPCS CODES IMPLEMENTED IN JULY 2008

CY 2008 HCPCS code	CY 2009 HCPCS code	CY 2009 long descriptor	Final CY 2009 status indicator	Final CY 2009 APC
C9242	J1453	Injection, fosaprepitant, 1 mg	G	9242
C9356	C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter.	G	9356
C9357	Q4114	Allograft, Integra Flowable Wound Matrix, injectable, 1 cc	G	1251
C9358	C9358	Dermal substitute, native, non-denatured collagen (SurgiMend Collagen Matrix), per 0.5 square centimeters.	G	9358
G0398	G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation.	S	0213
G0399	G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation.	S	0213
G0400	G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels.	S	0213

2. Treatment of New Category I and III CPT Codes and Level II HCPCS Codes

As has been our practice in the past, we implement new Category I and III CPT codes and new Level II HCPCS codes, which are released in the summer through the fall of each year for annual updating, effective January 1, in the final rule with comment period updating the OPPS for the following calendar year. 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, the APC assignment, or both, for all such codes flagged with comment indicator ''NI'' are open to public comment in this final rule with comment period. In the CY 2009 OPPS/ASC proposed rule (73 R 41468), we proposed to continue this recognition and process for CY 2009. New Category I and III CPT codes, as well as new Level II HCPCS codes, effective January 1, 2009, are listed in Addendum B to this final rule with comment period and designated using comment indicator ''NI.'' We will respond to all comments received concerning these codes in a subsequent final rule for the next calendar year's OPPS/ASC update.

In addition, in the CY 2009 OPPS/ASC proposed rule (73 FR 41468), we proposed to continue our policy of the last 3 years of recognizing new mid-year CPT codes, generally Category III CPT codes, that the AMA releases in January for implementation the following July through the OPPS quarterly update process. Therefore, for CY 2009, we proposed to include in Addendum B to this final rule with comment period the new Category III CPT codes released in January 2008 for implementation on July 1, 2008 (through the OPPS quarterly update process), and the new Category III codes released in July 2008 for implementation on January 1, 2009. However, only those new Category III CPT codes implemented effective January 1, 2009, are flagged with comment indicator ''NI'' in Addendum B to this final rule with comment period, to indicate that we have assigned them an interim payment status which is subject to public comment. Category III CPT codes implemented in July 2008, which appeared in Table 12 of the CY 2009 OPPS/ASC proposed rule and now in Table 14 below, were open to public comment in the proposed rule, and we are finalizing their CY 2009 status in this final rule with comment period.

We did not receive any public comments on the proposed CY 2009 assignment of status indicator ''M'' to CPT codes 0188T (Remote real-time interactive videoconferenced critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) and 0189T (Remote real-time interactive videoconferenced critical care, evaluation and management of the critically ill or

critically injured patient; each additional 30 minutes) and on the assignment of status indicator ''T'' to CPT code 0190T (Placement of intraocular radiation source applicator) in APC 0237 (Level II Posterior Segment Eye Procedures). Therefore we are finalizing these proposed assignments for CY 2009, without modification.

Comment: One commenter was concerned with the proposed assignment of new CPT code 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach) to APC 0234 (Level III Anterior Segment Eye Procedures) and recommended that the procedure be reassigned to APC 0673 (Level IV Anterior Segment Eye Procedures). According to the commenter, CPT code 0191T, which became effective July 1, 2008, uses a bypass device that routes fluid around the diseased part of a patient's aqueous drainage apparatus. The commenter indicated that there is significant resource dissimilarity between CPT code 0191T and other procedures assigned to APC 0234. The commenter argued that the procedure is more similar in resources to procedures assigned to APC 0673. The commenter explained that other procedures assigned to APC 0673 almost always use either a permanently implanted device or a permanent graft, while those assigned to APC 0234 do not. The commenter stated that CPT code 0191T requires the use of a costly implantable device, like other procedures assigned to APC 0673. The commenter also believed that the clinical characteristics of procedures already assigned to APC 0673 are more similar to CPT code 0191T than those assigned to APC 0234 because APC 0673 includes only procedures that treat glaucoma with intraocular surgery using a device to assist with aqueous outflow. According to the commenter, CPT code 66180 (Aqueous shunt to extraocular reservoir (e.g., Molteno, Schocket, Denver-Krupin)), which has the largest number of claims among procedures assigned to APC 0673, describes aqueous bypass surgery that serves the same purpose as the procedure described by CPT code 0191T. Finally, the commenter explained that the device used in CPT code 0191T is currently being studied in a FDA investigational device exemption (IDE) clinical trial.

Response: We assigned new Category III CPT code 0191T to APC 0234, effective July 1, 2008, and announced this assignment in the July 2008 OPPS update (Transmittal 1536, Change Request 6094, dated June 19, 2008). In the CY 2009 OPPS/ASC proposed rule (73 FR 41469), we proposed to continue this assignment for CY 2009 with a proposed payment rate of approximately $1,576. The commenter did not identify a predecessor CPT code for this surgical procedure, and there is limited clinical experience with this surgical procedure at this time. Nevertheless, based on our understanding of the clinical and resource characteristics of this surgical procedure, we continue to believe it is most appropriately assigned to APC 0234 in order to achieve the greatest clinical and resource homogeneity among the APC groups for anterior segment eye procedures. Further, we anticipate that the CY 2008 partial year hospital claims data for CPT code 0191T will first be available in CY 2009 for the CY 2010 OPPS/ASC rulemaking cycle. At that time we will review the assignment of this CPT code for CY 2010.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to assign CPT code 0191T to APC 0234, with a final CY 2009 APC median cost of approximately $1,543.

Comment: Many commenters requested that CPT code 0192T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach) be reassigned to APC 0673 (Level IV Anterior Segment Eye Procedures) from APC 0234 (Level III Anterior Segment Eye Procedures), where it was proposed for CY 2009 assignment. Several commenters reported that prior to July 1, 2008, when CPT code 0192T became effective, most providers reported this procedure with CPT code 66180 (Aqueous shunt to extraocular reservoir (e.g., Molteno, Schocket, Denver-Krupin)).

One commenter calculated a median cost of $2,806 using 19 single procedure OPPS claims for anterior segment eye procedures from 13 hospitals that the commenter believed represent services that would now be reported with CPT code 0192T. The commenter concluded that the analysis supported the request to assign CPT code 0192T to APC 0673, which had a proposed rule median cost of $2,631, while APC 0234 had a proposed rule median cost of only $1,573. The commenter pointed out that 17 of the 19 CY 2007 claims used for the analysis were coded with CPT code 66180, which was proposed for assignment to APC 0673 for CY 2009, indicating that the procedure and device costs of CPT code 0192T were reflected in claims data for APC 0673. The commenter estimated that about one third of the CY 2007 claims for CPT code 66180 represent procedures that would now be reported with CPT code 0192T. Furthermore, the commenter asserted that none of the procedures currently assigned to APC 0234 includes either a permanently implanted or high cost disposable device, while procedures assigned to APC 0673 utilize such devices.

The commenter also believed that the procedures assigned to APC 0673 are more clinically similar to CPT code 0192T than those assigned to APC 0234. The commenter noted that APC 0673 contains procedures, such as CPT code 66180, which primarily treat glaucoma with intraocular surgery using a device that assists with aqueous outflow. The commenter believed that assignment of CPT code 0192T to APC 0234 could result in limited patient access to that procedure.

Some commenters argued that payment for the aqueous shunt device should be paid separately from the hospital payment for the surgical procedure. Many commenters believed that the procedure described by CPT code 0192T is safer, more effective, and has fewer complications than trabeculectomy because the new procedure does not excise tissue but instead uses a shunt to bypass the trabecular tissue.

Response: We assigned new Category III CPT code 0192T to APC 0234 effective July 1, 2008, and announced this assignment in the July 2008 OPPS update (Transmittal 1536, Change Request 6094, dated June 19, 2008). In the CY 2009 OPPS/ASC proposed rule (73 FR 41469), we proposed to continue this APC assignment for new CPT code 0192T, with a proposed payment rate of approximately $1,576 for CY 2009. We agree with the commenters that new CPT code 0192T has associated implantable device costs that may not be fully reflected in the costs of other services assigned to APC 0234. It is our established OPPS policy to package payment for all implantable devices without pass-through status into payment for the associated surgical procedures. Therefore, we will not provide separate payment under the OPPS for the aqueous shunt required for CPT code 0192T. Moreover, CPT code 66180, which is assigned to APC 0673 for CY 2009, reportedly was often used to bill Medicare prior to July 1, 2008, for the procedure now described by CPT code 0192T. Therefore, the costs of CPT code 66180 from hospital claims data may partially reflect the costs of CPT code 0192T, as these two CPT codes are clinically similar. CPT code 66180 has a final CY 2009 median cost of approximately $2,772 and APC 0673 has a median cost of approximately $2,644.

Therefore, we agree with the commenters that APC 0673 is the most appropriate APC assignment for CPT code 0192T for CY 2009.

After consideration of the public comments received, we are modifying our CY 2009 proposal for payment of CPT 0192T and reassigning it to APC 0673, with a final CY 2009 APC median cost of approximately $2,644.

The final CY 2009 status indicators and APC assignments of the Category III CPT codes implemented in July 2008 are included in Table 14, below, as well as in Addendum B to this final rule with comment period.

TABLE 14—CATEGORY III CPT CODES IMPLEMENTED IN JULY 2008

CY 2009 HCPCS code	CY 2009 long descriptor	Final CY 2009 status indicator	Final CY 2009 APC
0188T	Remote real-time interactive videoconferenced critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes.	M	Not applicable.
0189T	Remote real-time interactive videoconferenced critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes.	M	Not applicable.
0190T	Placement of intraocular radiation source applicator	T	0237.
0191T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach.	T	0234.
0192T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach.	T	0673.

B. OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient services. Section 1833(t)(2)(B) of the Act provides that this classification system may be composed of groups of services, so that services within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as 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 final rule with comment period); (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.4. of this final rule with comment period.

In CY 2008, we implemented composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Under current CY 2008 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, and mental health services. In the CY 2009 OPPS/ASC proposed rule (73 FR 41450), we also proposed a composite APC payment methodology for multiple imaging services for CY 2009. Further discussion of composite APCs is included in section II.A.2.e. of this final rule with comment period.

Under the OPPS, we generally pay for hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. Each APC weight represents the hospital 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 clinic visit APC (that is, where the Level 3 clinic visit CPT code of five levels of clinic visits is assigned), and because middle level 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 the components of the OPPS not less than annually and to revise the groups and relative payment weights and make other adjustments to take into account changes in medical practice, changes in technology, and 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 outside panel of experts to review the APC groups and the relative payment weights (the APC Panel recommendations for specific services for the CY 2009 OPPS and our responses to them are discussed in the relevant specific sections throughout this final rule with comment period).

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest 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 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.

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 (''2 times rule''). In the CY 2009 OPPS/ASC proposed rule (73 FR 41469), we proposed to make exceptions to this limit on the variation of costs within each APC group in unusual cases such as low-volume items and services for CY 2009.

During the APC Panel's March 2008 meeting, we presented median cost and utilization data for services furnished during the period of January 1, 2007, through September 30, 2007, 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 2009 are contained mainly in sections III.C. and III.D. of this final rule with comment period.

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 proposed changes to their HCPCS codes' APC assignments in Addendum B to the CY 2009 OPPS/ASC proposed rule. In these cases, to eliminate a 2 times violation or to improve clinical and resource homogeneity, we proposed to reassign the codes to APCs that contain services that are similar with regard to both their clinical and resource characteristics (73 FR 41470). In the CY 2009 OPP/ASC proposed rule (73 FR 41470), we also proposed to rename existing APCs, discontinue existing APCs, or create new clinical APCs to complement proposed HCPCS code reassignments for CY 2009. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2009 included in the CY 2009 OPPS/ASC proposed rule were related to changes in median costs of services that were observed in the CY 2007 claims data newly available for the CY 2009 ratesetting. We also proposed changes to the status indicators for some codes that were not specifically and separately discussed in the proposed rule. In these cases, we proposed to change the status indicators for some codes because we believed that another status indicator would more accurately describe their payment status from an OPPS perspective based on the policies that we proposed for CY 2009 or because we proposed new status indicators to differentiate a related group of services from other services that previously shared the same status indicator (73 FR 41470).

Addendum B to the CY 2009 OPPS/ASC proposed rule identified with comment indicator ''CH'' those HCPCS codes for which we proposed a change to the APC assignment or status indicator as assigned in the April 2008 Addendum B update (via Transmittal 1487, Change Request 5999, dated April 8, 2008). HCPCS codes with proposed CY 2009 changes in status indicator assignments from ''Q'' to ''Q1,'' from ''Q'' to ''Q2,'' or from ''Q'' to ''Q3'' were an exception to this identification practice because they were not flagged with comment indicator ''CH'' in Addendum B to the CY 2009 OPPS/ASC proposed rule. Because these proposed changes in status indicators were designed to facilitate policy transparency and operational logic rather than to reflect changes in OPPS payment policy for these services, we believed that identifying these HCPCS codes with ''CH'' could be confusing to the public.

We received several public comments on our proposed separation of status indicator ''Q'' into three distinct status indicators, specifically ''Q1,'' ''Q2,'' or ''Q3,'' for purposes of policy transparency and administrative ease. This proposal, including the public comments received and our response to them, is discussed in section XIII.A. of this final rule with comment period.

3. Exceptions to the 2 Times Rule

As discussed earlier, we may make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases such as low-volume items and services. Taking into account the APC changes that we proposed for CY 2009 based on the APC Panel recommendations discussed mainly in sections III.C. and III.D. of this final rule with comment period, the other proposed changes to status indicators and APC assignments as identified in Addendum B to the CY 2009 OPPS/ASC proposed rule, and the use of CY 2007 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).

Table 13 of the CY 2009 OPPS/ASC proposed rule listed 12 APCs that we proposed to exempt from the 2 times rule for CY 2009 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 2007 claims data used to determine the APC payment rates that we proposed for CY 2009. The median costs for hospital outpatient services for these and all other APCs that were used in the development of the CY 2009 OPPS/ASC proposed rule and this final rule with comment period can be found on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/01_overview.asp*.

For the CY 2009 OPPS/ASC proposed rule, we based the listed exceptions to the 2 times rule on claims data from January 1, 2007, through September 30, 2007. For this final rule with comment period, we used claims data from January 1, 2007, through December 1, 2007. Thus, after responding to all of the public comments on the CY 2009 OPPS/ASC proposed rule and making changes to APC assignments based on those comments, we analyzed the CY 2007 claims data used for this final rule with comment period to identify the APCs with 2 times rule violations.

Based on the final CY 2007 claims data, we found that there were 14 APCs with 2 times rule violations, an increase of 2 APCs from the proposed rule. We have not included in this count those APCs where a 2 times violation is not a relevant concept, such as APC 0375 (Ancillary Outpatient Service When Patient Expires), with an APC median cost set based on multiple procedure claims, so that we have identified only final APCs, including those with

criteria-based median costs, such as device-dependent APCs, with 2 times violations. We applied the criteria as described earlier to identify the APCs that are exceptions to the 2 times rule for CY 2009, and as noted below, have identified the additional APCs that have met the criteria for exception to the 2 times rule for this final rule with comment period. These APC exceptions are listed in Table 15 below.

Comment: One commenter supported the continued exception of APC 0303 (Treatment Device Construction) to the 2 times rule for CY 2009. The commenter agreed that, based on the CY 2007 claims data, CMS' proposed assignment of the following three CPT codes to APC 0303 was appropriate: 77332 (Treatment devices, design and construction; simple (simple block, simple bolus)); 77333 (Treatment devices, design and construction; intermediate (multiple blocks, stents, bite blocks, special bolus)); and 77334 (Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)). Noting that the 2 times violation was not extreme, the commenter believed that the proposed exception was appropriate because the services within APC 0303 are clinically comparable.

Response: We appreciate the commenter's support for our proposal.

After consideration of all of the public comments received and our review of the CY 2007 claims data used for this final rule with comment period, we are finalizing our proposal to exempt 12 APCs from the 2 times rule for CY 2009, with modification. We are increasing the list of APC exceptions from 12 to 14 APCs to also include APCs 0341 (Skin Tests) and 0367 (Level I Pulmonary Test) for CY 2009. Our final list of the 14 APC exceptions to the 2 times rule for CY 2009 is displayed in Table 15 below.

TABLE 15—FINAL APC EXCEPTIONS TO THE 2 TIMES RULE FOR CY 2009

Final CY 2009 APC	CY 2009 APC title
0060	Manipulation Therapy.
0080	Diagnostic Cardiac Catheterization.
0093	Vascular Reconstruction/Fistula Repair Without Device.
0105	Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices.
0141	Level I Upper GI Procedures.
0245	Level I Cataract Procedures Without IOL Insert.
0303	Treatment Device Construction.
0330	Dental Procedures.
0341	Skin Tests.
0367	Level I Pulmonary Test.
0409	Red Blood Cell Tests.
0426	Level II Strapping and Cast Application.
0432	Health and Behavior Services.
0604	Level 1 Hospital Clinic Visits.

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 increments, which are in two parallel sets of New Technology APCs, one with status indicator ''S'' and the other with status indicator ''T,'' allow us to price new technology services more appropriately and consistently.

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

As we explained in the November 30, 2001, final rule (66 FR 59897), we generally keep a procedure in the New Technology APC to which it is initially assigned until we have collected sufficient data to enable us to move the procedure to a clinically appropriate APC. However, in cases where we find that our original New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that most appropriately reflects its cost.

Consistent with our current policy, in the CY 2009 OPPS/ASC proposed rule (73 FR 41471), we proposed to retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to a clinically appropriate APC for CY 2009. 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 hospital claims data upon which to base a decision for reassignment have not been collected.

We did not receive any public comments on this proposal. Therefore, we are finalizing our CY 2009 proposal, without modification, to retain services within New Technology APCs until we gather sufficient claims data to assign the services to a clinically appropriate APC. Thus, a service can be assigned to a New Technology APC for more than 2 years if we have insufficient claims data to reassign the service to a clinical APC, or it could be reassigned to a clinical APC in less than 2 years if we have adequate claims data.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41471), we stated that we believed we had sufficient claims data to propose reassigning the following three HCPCS codes, which we stated represent services assigned to New Technology APCs in CY 2008, to

clinically appropriate APC for CY 2009: C9725 (Placement of endorectal intracavitary applicator for high intensity brachytherapy), C9726 (Placement and removal (if performed) of applicator into breast for radiation therapy), and C9727 (Insertion of implants into the soft palate; minimum of three implants). These three procedures have been assigned to their New Technology APCs for at least 3 years, thereby providing us with data from at least 2 years of hospital claims upon which we based the proposed reassignments for CY 2009. In addition, as we indicated in the CY 2009 OPPS/ASC proposed rule, we believe that these three procedures are clinically similar to other services currently paid through clinical APCs under the OPPS and for which we have substantial claims data regarding hospital costs. Therefore, in the CY 2009 OPPS/ASC proposed rule , we proposed to reassign these three procedures to clinically appropriate APCs, utilizing their CY 2007 claims data to develop the clinical APC median costs upon which payments would be based for CY 2009. As shown in Table 14 of the CY 2009 OPPS/ASC proposed rule, we proposed to reassign HCPCS code C9725 from New Technology APC 1507—Level VII ($500–$600) to APC 0164 (Level II Urinary and Anal Procedures), with a proposed payment rate of approximately $145; to reassign HCPCS code 9726 from New Technology APC 1508—Level VIII ($600–$700) to APC 0028 (Level I Breast Surgery), with a proposed payment rate of approximately $1,412; and to reassign HCPCS code C9727 from New Technology 1510–Level X ($800–$900) to APC 0252 (Level III ENT Procedures), with a proposed payment rate of approximately $509.

Further, in the CY 2009 OPPS/ASC proposed rule (73 FR 41471), we proposed to delete HCPCS code C9723 (Dynamic infrared blood perfusion imaging (diri)) that has been assigned to New Technology APC 1502 (New Technology—Level II ($50–$100)) since it was implemented in April 2005. Based on our claims data for the past 3 years, which have shown no utilization for HCPCS code C9723, we proposed to delete this HCPCS code on December 31, 2008.

Comment: Several commenters disagreed with the proposed reassignment of HCPCS code C9725 and asserted that the CY 2007 claims data included only two single claims for HCPCS code C9725 and, therefore, these data provided an insufficient basis for reassigning this service from New Technology APC 1507 to APC 0164, which has a proposed payment rate of approximately $145. They argued that the procedures in APC 0164 are not clinically similar or comparable in cost to HCPCS code C9725. The commenters believed that the procedures included in APC 0164 require less time and physician skill than HCPCS code C9725 and that they do not require the use of a temporary implanted device for treatment delivery as does HCPCS code C9725. The commenters recommended that, for CY 2009, CMS retain HCPCS code C9725 in its current New Technology APC with a payment rate of approximately $550 for at least 1 more year, or reassign it to APC 0155 (Level II Anal/Rectal Procedures), which has a proposed payment rate of approximately $804, because they believed that APC 0155 would be a more appropriate assignment for HCPCS code 9725 based on consideration of its clinical characteristics and resource costs.

Response: We do not agree that that we should continue to assign HCPCS code C9725 to New Technology APC 1507, as explained below. HCPCS code C9725 was assigned to New Technology 1507 with a payment rate of approximately $550 when it was implemented on October 1, 2005. At this point, the service has been assigned to a New Technology APC for over 3 years. We believe that reassigning this service to a clinical APC is appropriate for CY 2009, because this service is clinically similar to other services currently paid under the OPPS and because it has resided in a New Technology APC for over 3 years.

At the August 2008 APC Panel meeting, a public comment letter on the CY 2009 OPPS/ASC proposed rule was discussed that requested that the APC Panel recommend that CMS reassign HCPCS code C9725 to APC 0155 (Level II Anal/Rectal Procedures) rather than to APC 0164, as proposed, on the basis of its clinical similarity to other procedures in APC 0155. The proposed CY 2009 payment rate of APC 0155 is approximately $804. The APC Panel did not agree that HCPCS code C9725 is comparable to the procedures in APC 0155, but the APC Panel recommended that CMS reassign the HCPCS code C9725 to an appropriate device-dependent APC based on median cost data.

Further analysis of the latest CY 2007 claims data used for this final rule with comment period revealed limited data for HCPCS code C9725, with variable costs over the past 3 years, leading us to conclude that this service is rarely performed on Medicare beneficiaries in the HOPD. We do not agree with the commenters' recommendation to either retain this procedure in New Technology APC 1507 for 1 more year or to reassign it to clinical APC 0155 in the Anal/Rectal Procedures series for CY 2009. Currently we do not have an identified device-dependent APC under the OPPS that would be an appropriate assignment for HCPCS code C9725, and there is no Level II HCPCS code that describes the device that is inserted into the body that would be reported with the procedure. Therefore, we are not adopting the APC Panel's recommendation to assign the service to an appropriate device-dependent APC for CY 2009.

However, after reexamining the clinical characteristics of HCPC code C9725, the limited claims data, and our expectations regarding the cost of the procedure, we reevaluated our proposed assignment for HCPCS code C9725 and believe that this service would be more appropriately assigned to APC 0148 (Level I Anal/Rectal Procedures), based on considerations of the service's clinical and resource characteristics. Moreover, several commenters recommended an APC assignment for HCPCS code C9725 in this same clinical series. APC 0148 has a final median cost of approximately $378 for CY 2009, and we believe this APC will ensure appropriate payment for HCPCS code C9725.

After consideration of the public comments received and the APC Panel recommendation, in this final rule with comment period, we are modifying our CY 2009 proposal and reassigning HCPCS code C9725 to APC 0148 (instead of APC 0164), with a final CY 2009 APC median cost of approximately $378 for CY 2009.

Comment: One commenter supported the proposed reassignment of HCPCS code C9726 from New Technology APC 1508 to APC 0028 for CY 2009, with a proposed payment rate of approximately $1,412.

Response: We appreciate the commenter's support.

After consideration of the public comment received, we are finalizing our CY 2009 proposal, without modification, to reassign HCPCS code C9726 to APC 0028, with a final CY 2009 APC median cost of approximately $1,387.

We did not receive any public comments on the proposed assignment of HCPCS code C9727 to APC 0252 or our proposal related to the deletion of HCPCS code C9723. Therefore, we are finalizing our CY 2009 proposals, without modification, to reassign HCPCS code C9727 to APC 0252, which has a final CY 2009 APC median cost of approximately $486 and to discontinue HCPCS code C9723 on December 31,

2008. Table 16, below, lists the final CY 2009 APC assignments and status indicators for HCPCS codes C9725, C9726, and C9727.

TABLE 16—CY 2009 APC REASSIGNMENTS OF NEW TECHNOLOGY PROCEDURES TO CLINICAL APCS

CY 2009 HCPCS code	CY 2009 short descriptor	CY 2008 SI	CY 2008 APC	Final CY 2009 SI	Final CY 2009
C9725	Placement of endorectal intracavitary applicator for high intensity brachytherapy.	S	1507	T	0148
C9726	Placement and removal (if performed) of applicator into breast for radiation therapy.	S	1508	T	0028
C9727	Insertion of implants into the soft palate; minimum of three implants.	S	1510	T	0252

D. OPPS APC-Specific Policies

1. Apheresis and Stem Cell Processing Services

a. Low-Density Lipoprotein (LDL) Apheresis (APC 0112)

In the CY 2009 OPPS/ASC proposed rule (73 FR 41798), we proposed to continue our CY 2008 assignment of CPT code 36516 (Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion) to APC 0112 (Apheresis and Stem Cell Procedures) with a proposed payment rate of approximately $2,020. The CY 2008 payment rate for this service is approximately $1,949.

Comment: One commenter argued that the CY 2007 claims data for CPT code 36516 are skewed and would result in a CY 2009 payment rate for APC 0112 that is unacceptably low for hospitals. The commenter stated that LDL apheresis is the only procedure that can be reported accurately using CPT code 36516. According to the commenter, far fewer hospitals have the capability to perform this procedure than hospitals that are billing CPT code 36516 on OPPS claims. Furthermore, the commenter asserted that hospitals systematically underreport costs for CPT code 36516, resulting in a median cost for CPT code 36516 that is undervalued by an estimated $1,000, and a median cost for APC 0112 that is undervalued by an estimated $150 to $200. The commenter recommended that CMS initiate an investigation or provide instruction on how to rectify the misreporting of the procedure described by CPT code 36516, and remove all claims for CPT code 36516 from the median calculation upon which the payment rate for APC 0112 is based.

Response: We do not believe it is necessary to alter our standard OPPS ratesetting methodology to exclude claims for CPT code 36516 from the median cost calculation for APC 0112 in order to ensure appropriate payment to hospitals that will ensure access to care in CY 2009. The payment rate for APC 0112 has steadily increased since CY 2006, when the OPPS payment rate was approximately $1,570. We also note that procedures described by CPT code 36516 comprise only 11 percent of the CY 2007 single claims for all services that are used to calculate the median cost of APC 0112. Furthermore, according to the commenter's analysis, removing several hundred claims for CPT code 36516 from the calculation of the median cost of APC 0112 would lead to only a small change of $150 to $200 in the APC's median cost.

We have no reason to believe that hospitals are misreporting services with CPT code 36516 and note that we do not specify the methodologies that hospitals must use to set charges for this, or any other, procedure. The calculation of OPPS payment weights that reflect the relative resources required for HOPD services is the foundation of the OPPS, and we also see no reason why hospitals would systemically underreport the costs of the procedure described by CPT code 36516.

We rely on hospitals to bill all HCPCS codes accurately in accordance with their code descriptors and CPT and CMS instructions, as applicable, and to report charges on claims and charges and costs on their Medicare cost report appropriately. In both the January 2005 OPPS quarterly update, Transmittal 423, Change Request 3632, issued on January 6, 2005, and the January 2006 OPPS quarterly update, Transmittal 804, Change Request 4250, issued on January 3, 2006, we provided instructions to hospitals on how to correctly report items and services associated with the procedure described by CPT code 36516. Specifically, we instructed hospitals to bill supply charges either by including them in the charge for CPT code 36516 or by using an appropriate supply revenue code when using CPT code 36516 to report extracorporeal selective absorption of selective filtration and plasma reinfusion for indications such as familial hypercholesterolemia. We further emphasized that, in every case, hospitals should report the codes that most accurately describe the therapeutic apheresis service that is being furnished. We continue to expect hospitals to report the services described by CPT code 36516 accurately as we have instructed, and see no current basis for questioning the charges hospitals report on their claims and on their Medicare cost reports for this service.

After consideration of the public comment received, we are finalizing our CY 2009 proposal, without modification, to calculate the payment rate for APC 0112 by applying our standard OPPS ratesetting methodology that relies on all single claims for all procedures assigned to the APC. The final CY 2009 median cost of APC 0112 is approximately $1,988.

b. Bone Marrow and Stem Cell Processing Services (APC 0393)

For CY 2008, we discontinued recognizing HCPCS code G0267 (Bone marrow or peripheral stem cell harvest, modification or treatment to eliminate cell type(s)) for depletion services for hematopoietic progenitor cells) for payment under the OPPS and deleted the HPCPCS code effective January 1, 2008 (72 FR 66821 through 66823). Instead, we recognized the specific CPT codes that describe these services, which include: CPT codes 38210 (Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion); 38211 (Transplant preparation of hematopoietic progenitor cells; tumor cell depletion); 38212 (Transplant preparation of hematopoietic progenitor cells; red blood cell removal); 38213 (Transplant preparation of hematopoietic progenitor cells; platelet depletion); 38214 (Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion); and 38215 (Transplant preparation of hematopoietic progenitor cells; cell

concentration in plasma, mononuclear, of buffy coat layer).

For CY 2008, we assigned CPT codes 38210 through 38215 to APC 0393 with other red blood cell and plasma handling and testing services and renamed APC 0393 ''Hematologic Processing and Studies'' so that the APC title more accurately describes all the services assigned to the APC. We maintained a status indicator of ''S'' for APC 0393. The data for the predecessor code, HCPCS code G0267, was also assigned to APC 0393. The CY 2008 payment for APC 0393 is approximately $363, based on an APC median cost of approximately $397, the same median cost as HCPCS code G0267 in CY 2008. As we stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66823), it is consistent with our general practice under the OPPS to make payment based on historical claims data for the predecessor HCPCS code until we have more specific hospital resource data available to assess the specific CPT codes for possible APC reassignment. In the CY 2009 OPPS/ASC proposed rule, we did not propose to change the APC assignments for CPT codes 38210 through 38215 for CY 2009. The CY 2009 proposed payment for APC 0393 was approximately $398.

Comment: One commenter asserted that CPT codes 38210 and 38211 were inappropriately assigned to APC 0393 because the other services in APC 0393 are not related to stem cell purification and transplantation and because the supplies and clinical staff costs are significantly more than the proposed payment rate for these two services. The commenter recommended that CMS reassign these services to APC 0112 (Apheresis and Stem Cell Procedures), reasoning that the codes for T-cell and tumor cell depletion are more similar clinically and in terms of costs to other services assigned to APC 0112.

Response: As we stated in the CY 2008 OPS/ASC final rule with comment period (72 FR 66823), we believe that our assignment of CPT codes 38210 through 38215 to APC 0393 will pay appropriately for these CPT codes while we collect more specific data on their individual resource costs. We continue to believe that the two specific services for T-cell or tumor cell depletion during preparation of hematopoietic progenitor cells for transplantation are more clinically similar to those services in APC 0393 than in APC 0112, which contains procedures for extracorporeal adsorption during therapeutic apheresis that involves reinfusion of plasma into the patient and bone marrow and stem cell collection and transplantation, rather than cell processing. We note that the final median cost for APC 0112 for CY 2009, is approximately $1,988, while the final median cost for APC 0393 is approximately $391. There were no claims submitted for CPT code 38210 in CY 2008. In addition, there was one claim for CPT code 38211 available for ratesetting, with a median cost of about $201. Further, there were 125 claims for HCPCS code G0267 available for ratesetting, with a final median cost of $391. Based on these cost data, we continue to believe that APC 0393 will pay more appropriately for CPT codes 38210 and 38211 while we collect more specific data on their individual resource costs.

After consideration of the public comment received, we are finalizing our CY 2009 proposal, without modification, to maintain CPT codes 38210 and 38211 in APC 0393, with a final CY 2009 APC median cost of approximately $391.

2. Genitourinary Procedures

a. Implant Injection for Vesicoureteral Reflux (APC 0163)

Following publication of the CY 2008 OPPS/ASC final rule with comment period, several members of the public contacted us to express their concerns regarding inadequate payment for CPT code 52327 (Cystourethroscopy, including ureteral catheterization, with subureteric injection of implant material). The CY 2008 OPPS payment for this procedure, which is assigned to APC 0162 (Level III Cystourethroscopy and other Genitourinary Procedures), is approximately $1,578. From the perspective of these stakeholders, the CY 2008 assignment of CPT code 52327 to APC 0162 provides inadequate payment to cover the hospital's cost for the procedure, which they asserted requires expensive implant material. Specifically, they stated that the currently available CPT and Level II HCPCS codes lack the specificity needed to properly account for the cost of the ureteral implant, dextranomer/hyaluronic acid, the only FDA approved product for the procedure. In addition to receiving several letters on this subject, we also met with stakeholders about the concerns of pediatric urologists regarding decreased access to and inadequate payment for performance of this procedure.

At the March 2008 APC Panel meeting, a presenter requested that the APC Panel recommend reassignment of CPT code 52327 from APC 0162 to APC 0385 (Level I Prosthetic Urological Procedures). The presenter indicated that while CPT code 52327 is clinically similar to other procedures assigned to APC 0162, it is not similar in terms of resource utilization. The presenter stated that CPT code 52327 is the only procedure assigned to APC 0162 that uses a high cost implant, with a stated cost of $1,045 per milliliter. The APC Panel recommended that CMS consider reassigning CPT code 52327 to a more appropriate APC.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41477), we proposed to reassign CPT code 52327 from APC 0162 to APC 0163 (Level IV Cystourethroscopy and other Genitourinary Procedures), with a proposed payment rate of approximately $2,392.

Comment: One commenter supported the proposed reassignment of CPT code 52327 from APC 0162 to APC 0163. However, the commenter expressed concern that the proposed payment rate for the service is still inadequate. The commenter contended that until hospitals are able to report the implant material with a separate HCPCS code, the procedure would continue to be inadequately paid under APC 0163. Another commenter also expressed support for the proposed reassignment of CPT code 52327 to APC 0163 from APC 0162. However, the commenter noted that the proposed increase in payment was less than the cost of a single vial of the implant material and that it is not uncommon for more than one vial to be used during a procedure. The commenter argued that Medicare claims data do not accurately reflect the cost of the implant for several reasons, specifically that the procedure is primarily a pediatric procedure with few Medicare claims and that there is no unique HCPCS code to describe the implant product.

Response: We appreciate the commenters' support for our proposal to reassign CPT code 52327 from APC 0162 to APC 0163 for CY 2009. We continue to believe that APC 0163 will provide appropriate payment for this surgical procedure, including the cost of the ureteral implant material, in CY 2009. As we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41477), a number of the procedures also assigned to APC 0163 are clinically similar to CPT code 52327, involving the use of a cystoscope and the implantation of devices.

There is a new Level II HCPCS code for CY 2009, HCPCS code L8604 (Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml), that describes an implant that may be used in the procedure reported with CPT code 52327. However, with the exception of implantable devices that are subject to

transitional pass-through payment for a limited time period, under the OPPS, regardless of the availability of HCPCS codes specific to implantable devices, Medicare makes payment for those implantable devices through payment for the associated surgical procedure. According to our regulations at § 419.2(b), 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. Therefore, HCPCS code L8604 is assigned an interim CY 2009 status indicator of ''N'' in Addendum B to this final rule with comment period, to indicate that its payment is unconditionally packaged in all cases. We also note that, because HCPCS code L8604 is a new code for CY 2009, it is assigned comment indicator ''NI'' in Addendum B to this final rule with comment period, indicating that its interim OPPS treatment is open to public comment on this final rule with comment period.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to reassign CPT code 52327 from APC 0162 to APC 0163, with a final CY 2009 APC median cost of approximately $2,316.

b. Laparoscopic Ablation of Renal Mass (APC 0132)

In the CY 2009 OPPS/ASC proposed rule, we proposed to continue the assignment of CPT code 50542 (Laparoscopy, surgical; ablation of renal mass lesion(s)) to APC 0132 (Level III Laparoscopy), with a proposed payment rate of approximately $4,715. The CY 2008 payment rate for APC 0132 is approximately $4,437.

Comment: Several commenters disagreed with the proposed continued assignment of CPT code 50542 to APC 0132. They indicated that the service described by CPT code 50542 is not similar, in terms of clinical characteristics or resource costs, to the other procedures in APC 0132. The commenters further asserted that APC 0132 does not accurately reflect the hospital costs required to perform the procedure on an outpatient basis, which may be performed by cryoablation or radiofrequency ablation. They recommended that CMS create a new clinical APC in the laparoscopy series in order to improve both the clinical and resource homogeneity of the laparoscopy APCs and reassign CPT code 50542 to this new clinical APC.

Response: CPT code 50542 was implemented on January 1, 2003, and from CYs 2003 through 2005, this service was assigned to APC 0131 (Level II Laparoscopy). As discussed in the CY 2006 OPPS final rule with comment period (70 FR 68604), a CY 2006 OPPS proposed rule commenter recommended that we reassign CPT code 50542 from APC 0131 to APC 0132 to adequately pay for the cost of performing this procedure. We examined our CY 2004 hospital outpatient claims used for CY 2006 ratesetting and concluded that a reassignment to APC 0132 was warranted. For CY 2009, our analysis of the CY 2007 hospital outpatient claims data used for CY 2009 ratesetting revealed a HCPCS code-specific median cost of approximately $8,225 for CPT code 50542, which is substantially higher than the APC median cost of approximately $4,515 for APC 0132. We also found, after further examination of all of the procedures currently assigned to APC 0132, that CPT code 47370 (Laparoscopy, surgical, ablation of one or more liver tumor(s); radiofrequency) that describes another laparoscopic ablation procedure has a HCPCS code-specific median cost of approximately $6,520, which is also significantly higher than the median cost for APC 0132. While there are numerous procedures assigned to APC 0132, most are low volume and only 1 procedure has significant volume consisting of 862 single claims, with a HCPCS code-specific median cost of approximately $4,651, significantly lower than the median costs of the 2 ablation procedures. Based on these findings, we believe that creation of a new clinical APC, specifically APC 0174 (Level IV Laparoscopy) with status indicator ''T,'' and the reassignment of both CPT codes 50542 and 47370 for laparoscopic ablation procedures to this new APC, are the most appropriate approaches to ensuring clinical and resource homogeneity within APC 0132 and new APC 0174.

After consideration of the public comments received, we are modifying our CY 2009 proposed configuration of APC 0132 by reassigning CPT codes 50542 and 47370 from APC 0132 to new clinical APC 0174 for laparoscopic procedures, which has a final CY 2009 APC median cost of approximately $7,731. Reconfigured APC 0132 has a final CY 2009 APC median cost of approximately $4,515.

c. Percutaneous Renal Cryoablation (APC 0423)

In the CY 2009 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 50593 (Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy) to APC 0423 (Level II Percutaneous Abdominal and Biliary Procedures) for CY 2009, with a proposed payment rate of approximately $3,028. This CPT code was new in CY 2008; however, the same service was previously described by CPT code 0135T (Ablation renal tumor(s), unilateral, percutaneous, cryotherapy). We note that in CY 2007, based upon the APC Panel's recommendation made at its March 2006 meeting, we reassigned CPT code 50593 (then CPT code 0135T) from APC 0163 (Level IV Cystourethroscopy and other Genitourinary Procedures) to APC 0423, with a payment rate of approximately $2,297 in CY 2007. We expected hospitals, when reporting CPT code 50593, to also report the device HCPCS code, C2618 (Probe, cryoablation), associated with the procedure.

Comment: Several commenters disagreed with the proposed continued APC assignment of CPT code 50593 to APC 0423. The commenters believed that the proposed payment rate for APC 0423 does not accurately reflect the costs incurred by hospitals that perform CPT code 50593, and recommended that CMS assign this procedure to its own APC and base payment for that APC on the mean cost of CPT code 50593. They also believed that the proposed inadequate payment rate for CPT code 50593 is attributable to the use of claims data that do not accurately capture the full costs of CPT code 50593.

Response: Based on our review of the procedures assigned to APC 0423, the public comments received, and the CY 2006 recommendation of the APC Panel regarding renal cryoablation, we believe that we have appropriately assigned CPT code 50593 to APC 0423 for CY 2009 based on clinical and resource considerations. We continue to believe that CPT code 50593 is appropriately assigned to APC 0423 because it is grouped with other procedures that share similar clinical and resource characteristics. Further examination of the procedures assigned to APC 0423 revealed that the HCPCS code-specific median costs of these services are all similar, ranging from $2,875 to $3,959.

In regard to the commenters' request that CMS assign CPT code 50593 to its own APC and provide payment based on the mean cost of this procedure, it has been our policy since the implementation of the OPPS that the

final APC relative weights and payment rates are based on median hospital costs, not mean costs, for the clinical APC groups. The OPPS relies on the relativity of costs for procedures as reported by hospitals in establishing payment rates, and we do not believe it would be appropriate to utilize a different payment methodology based on mean cost for one APC, while the payment rates for the other clinical APCs would be based on median costs. Mean and median costs are two different statistical measures of central tendency and, based on common distributions, mean costs typically are higher than median costs. Therefore, we do not believe it would be appropriate to use a combination of these measures to establish the payment weights for different clinical APCs under the OPPS.

Comment: Some commenters requested that CMS designate CPT code 50593 as a device-dependent procedure. They requested that CMS establish a claims processing edit to ensure that the device HCPCS code C2618 (Probe, cryoablation), used during the procedure, is reported on percutaneous renal cryoablation claims to ensure correctly coded claims for future ratesetting that accurately reflect hospitals' costs for CPT code 50593. Commenters indicated that the failure of hospitals to report the device HCPCS C-code for the cryoablation probe on claims leads to an underestimation of hospital costs for the procedure.

Response: We acknowledge the concerns raised by the commenters regarding hospitals' failure to report the device HCPCS code C2618 with the procedure in many cases. We further examined our CY 2007 claims data used for this final rule with comment period to determine the frequency of billing CPT code 50593 with and without HCPCS code C2618. Our analysis revealed that the CY 2009 final rule median cost for CPT code 50593 of approximately $3,959, based on 118 single bills used for CY 2009 ratesetting, falls within the range for those procedures billed with and without the device HCPCS code C2618. Specifically, our data showed a median cost of approximately $4,632 based on 48 single bills for procedures reported with the device HCPCS code C2618 and a median cost of about $2,924 based on 71 single bills for those procedures billed without the device HCPCS C-code. (We note that of the 119 single bills available for CY 2009 ratesetting, we trimmed 1 claim with excessively high cost when setting the CY 2009 final rule median.) Even considering only those claims for percutaneous renal cryoablation with the device HCPCS code and higher median cost, the procedure would be appropriately assigned to APC 0423 based on that cost. As a result of this analysis, which showed that both claim subsets could be appropriately mapped to APC 0423 based on their costs, we believe it continues to be appropriate to use all single claims for CPT code 50593 for ratesetting and that the procedure is appropriately assigned to APC 0423.

Further, we do not agree that we should create a claims processing edit for CPT code 50593 and HCPCS code C2618 for the cryoablation probe, nor do we believe that we should identify any individual HCPCS codes as device-dependent HCPCS codes under the OPPS for CY 2009. We create device edits, when appropriate, for procedures assigned to device-dependent APCs, where those APCs have been historically identified under the OPPS as having very high device costs. Because APC 0423 is not a device-dependent APC and the costs of percutaneous renal cryoablation with and without HCPCS code C2618 are both within the range of costs for procedures assigned to APC 0423, we are not creating claims processing edits for CY 2009. Furthermore, in the case of APC 0423, we note that while all of the procedures assigned to this APC require the use of implantable devices, for many of the procedures there are no Level II HCPCS codes that describe all of the technologies that may be used in the procedures. Therefore, it would not be possible for us to develop procedure-to-device edits for most of the CPT codes assigned to the APC.

We remind hospitals that they must report all of the HCPCS codes that appropriately describe the items used to provide services, regardless of whether the HCPCS codes are packaged or paid separately. If hospitals use more than one probe in performing CPT code 50593, we expect hospitals to report this information on the claim and adjust their charges accordingly. Hospitals should report the number of cryoablation probes used to perform CPT code 50593 as the units of HCPCS code C2618 which describes these devices, with their charges for the probes. Since CY 2005, we have required hospitals to report device HCPCS codes for all devices used in procedures if there are appropriate HCPCS codes available. In this way, we can be confident that hospitals have included charges on their claims for costly devices used in procedures when they submit claims for those procedures.

After consideration of all the public comments received, we are finalizing our CY 2009 proposal, without modification, to continue to assign CPT code 50593 to APC 0423, which has a final CY 2009 APC median cost of approximately $3,003.

d. Magnetic Resonance Guided Focused Ultrasound (MRgFUS) Ablation of Uterine Fibroids (APC 0067)

In the CY 2009 OPPS/ASC proposed rule, we proposed to continue to assign CPT codes 0071T (Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue) and 0072T (Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue) to APC 0067 (Level III Stereotactic Radiosurgery, MRgFUS, and MEG), with a payment rate of approximately $3,664. The CY 2008 payment rate for these services is approximately $3,930. Further, at its August 2008 meeting, the APC Panel recommended that CMS maintain the APC assignment for both procedures, specifically CPT codes 0071T and 0072T, to APC 0067, similar to the recommendation the APC Panel made for these procedures at its March 2007 meeting.

Comment: Several commenters commended CMS for its proposal to assign the MRgFUS procedures, specifically CPT codes 0071T and 0072T, to APC 0067 because of their clinical similarity to other services also assigned to that APC. However, the commenters disagreed with the proposed payment rate of $3,664 for these procedures. They claimed that the payment rate for the procedures continues to be lower than the hospital costs incurred to provide the services and does not accurately reflect all of the components required to perform the MRgFUS procedures. They asserted that the proposed payment rate does not include payment for the treatment planning required to perform the procedure. The commenters recommended that CMS reassign CPT codes 0071T and 0072T to another APC in the same clinical series, specifically APC 0127 (Level IV Stereotactic Radiosurgery, MRgFUS, and MEG), with a proposed payment rate of approximately $7,608, because assignment to this APC would provide more appropriate payment for the hospital resources needed to perform the procedures.

Response: We disagree that the MRgFUS procedures are clinically similar to the single multi-source cobalt-based stereotactic radiosurgery (SRS) service that is currently assigned to APC 0127, and which we believe requires significantly greater hospital resources.

The SRS procedure is generally performed on intracranial lesions, and requires immobilization of the patient's head using a frame that is applied to the skull. Several hundred converging beams of gamma radiation are then applied to the target lesion, requiring their accurate placement to the fraction of a millimeter. In contrast, during MRgFUS, magnetic resonance imaging guidance is utilized to confirm tissue heating, while multiple sonications at various points in the fibroid treatment area are executed until the entire target volume has been treated.

Our analysis of the latest CY 2007 hospital outpatient claims data indicates that MRgFUS procedures are rarely performed on Medicare beneficiaries. As we stated in the CY 2006 OPPS final rule with comment period (70 FR 68600) and in the CYs 2007 and 2008 OPPS/ASC final rules with comment period (71 FR 68050 and 72 FR 66710, respectively), because treatment of uterine fibroids is most common among women younger than 65 years of age, we expect very limited Medicare claims for these procedures. In fact, for claims submitted from CYs 2005 through 2007, our claims data showed that there were only two claims for CPT code 0071T in CY 2005, one claim in CY 2006, and again only one claim in CY 2007. There were no claims submitted for CPT code 0072T from CYs 2005 through 2007. Therefore, we have no reliable information from hospital claims regarding the costs of MRgFUS procedures. However, we continue to believe that the clinical and expected resource characteristics for these procedures resemble the first or complete session linear accelerator-based SRS treatment delivery services that also are assigned to APC 0067.

Further, in response to a public comment letter that was presented at its August 2008 meeting, the APC Panel reiterated its March 2007 recommendation to maintain the current placement of CPT codes 0071T and 0072T in APC 0067 for CY 2009. At that meeting, a stakeholder reported that the reason for requesting the reassignment of the MRgFUS procedures from APC 0067 to APC 0127 is to set the standard payment rate for other payers because many of them base their payment rates on Medicare rates. We remind hospitals that the payment rates set for the services, procedures, and items paid under the OPPS are based mainly on costs from hospitals' claims, and are established in accordance with the payment policies of the OPPS to provide appropriate payment for the care of Medicare beneficiaries. Non-Medicare payers set their own payment rates based on their payment policies.

After consideration of the public comments received and the APC Panel recommendations from its March 2007 and August 2008 meetings, we are finalizing our CY 2009 proposal, without modification, to continue to assign CPT codes 0071T and 0072T to APC 0067, with a final CY 2009 APC median cost of approximately $3,718.

e. Prostatic Thermotherapy (APC 0429)

In the CY 2009 OPPS/ASC proposed rule, we proposed to continue the assignment of CPT codes 53850 (Transurethral destruction of prostate tissue; by microwave thermotherapy) and 53852 (Transurethral destruction of prostate tissue; by radiofrequency thermotherapy) to APC 0429 (Level V Cystourethroscopy and other Genitourinary Procedures) for CY 2009, with a proposed payment rate of approximately $3,016.

Comment: One commenter, who stated that CPT codes 53850 and 53852 were assigned to APC 0163, urged CMS to investigate whether these procedures were correctly assigned to APC 0163 as the commenter believed that APC 0429 would be a more appropriate assignment for the procedures based on clinical and resource considerations. The commenter recommended that the APC assignments of CPT codes 53850 and 53852 be discussed at the next APC Panel meeting.

Response: As we stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66709), as part of our annual review, we examine the APC assignments for all items and services under the OPPS for appropriate placements in the context of our proposed policies for the update year. This review involves careful and extensive analysis of our hospital outpatient claims data, as well as input from our medical advisors, the APC Panel, and the public. As stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66709), we agreed with a commenter on the CY 2008 OPPS/ASC proposed rule that reassignment of CPT codes 53850 and 53852 to APC 0429 with a CY 2008 median cost of approximately $2,844 would be appropriate, based on their clinical and resource similarities with other procedures to destroy prostate tissue also residing in that APC. We proposed to continue to assign these two procedures to APC 0429 for CY 2009; therefore, our proposed assignment already reflected the commenter's requested assignment. Consequently, because CPT codes 53850 and 53852 are already assigned to APC 0429, we do not see the need to discuss this issue at the next APC Panel meeting.

After consideration of the public comment received, we are finalizing our CY 2009 proposal, without modification, to continue to assign CPT codes 53850 and 53852 to APC 0429, with a final CY 2009 APC median cost of approximately $2,958.

3. Nervous System Procedures

a. Magnetoencephalography (MEG) (APC 0067)

APC 0067 (Level III Stereotactic Radiosurgery, MRgFUS and MEG), with a proposed CY 2009 payment rate of approximately $3,664, contains five HCPCS codes: CPT code 95965 (Magnetoencephalography, recording and analysis; for spontaneous brain magnetic activity (e.g., epileptic cerebral cortex)); HCPCS code G0173 (Linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session); HCPCS code G0399 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment); CPT code 0071T (Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue); and CPT code 0072T (Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue). In March 2007, the APC Panel recommended that CPT code 95965 be placed in APC 0067. Given the clinical and resource similarities among CPT code 95965 and the other existing codes in APC 0067, we agreed and reassigned CPT code 95965 to APC 0067, to which it was assigned for the CY 2008 OPPS with a payment rate of approximately $3,930. At its August 2008 meeting, the APC Panel recommended that CMS retain CPT code 95965 in APC 0067 for CY 2009.

Comment: One commenter objected to the proposed reduction in payment for APC 0067, on the basis that it would reduce, by approximately $300, the CY 2009 payment for the service reported under CPT code 95965, compared to the CY 2008 payment rate. The commenter asked that CMS determine whether the claims from the hospital in which the commenter furnished services were included in the set of single bills used to calculate the proposed payment rate.

Response: Our final rule data show a median cost for APC 0067 of approximately $3,718 and a median cost for CPT code 95965 of approximately

$2,227. We agree with the APC Panel that CPT code 95965 is clinically compatible with the other services assigned to APC 0067 and that the median cost for CPT code 95965, while somewhat lower than the median costs of the other services also assigned to the APC, is consistent with the CPT code's assignment to APC 0067. The process we use to select the claims used in the calculation of the OPPS rates is discussed in section II. of this final rule with comment period. We make the claims we use for ratesetting available for public examination and analysis through the limited and identifiable OPPS data sets so that the public may review them if there are questions about particular claims used to set the rates under the OPPS. Information on these files is available on the CMS Web site at: *http://www.cms.hhs.gov/LimitedDataSets/06_HospitalOPPS.asp*.

After consideration of the public comment received, we are retaining the assignment of CPT code 95965 to APC 0067 for CY 2009, as recommended by the APC Panel, with a final CY 2009 APC median cost of approximately $3,718.

b. Chemodenervation (APC 0204)

In the CY 2009 OPPS/ASC proposed rule, we proposed to continue our assignment of CPT code 64612 (Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g., for blepharospasm, hemifacial spasm) to APC 0204 (Level I Nerve Injections), with a proposed payment rate of approximately $165. The CY 2008 payment rate for this service is approximately $148. In addition, for CY 2009, we proposed to reassign CPT codes 64613 (Chemodenervation of muscle(s); neck muscle(s) (e.g., for spasmodic torticollis, spasmodic dysphonia)) and 64614 (Chemodenervation of muscle(s); extremity(s) and/or trunk muscle(s) (e.g., for dystonia, cerebral palsy, multiple sclerosis)) from APC 0204 to APC 0206 (Level II Nerve Injections), with a proposed payment rate of approximately $243.

Comment: Several commenters requested that CMS reassign CPT code 64612 from APC 0204 to APC 0206, the same APC to which CMS proposed to assign CPT codes 64613 and 64614. Commenters claimed that CPT code 64612 is clinically similar and comparable in resource use to CPT codes 64613 and 64614 and, therefore, believed that CPT code 64612 should also be assigned to APC 0206.

Response: CPT code 64612 has a HCPCS code-specific median cost of approximately $138, based on over 5,000 single claims, and we proposed to assign this service to APC 0204, which has a final median cost of approximately $161. We believe that APC 0204 appropriately reflects the hospital resource characteristics of CPT code 64612 and provides appropriate payment to hospitals for this service. Further, we believe that other procedures currently assigned to APC 0204 are similar to CPT code 64612 with respect to their clinical characteristics.

In contrast, CPT code 64613 has a HCPCS code-specific median cost of approximately $197 based on approximately 5,700 single claims. Similarly, CPT code 64614 has a HCPCS code-specific median cost of approximately $217 based on over 5,700 single claims data. We proposed to assign both of these services to APC 0206, which has a final APC median cost of approximately $236. Our CY 2007 claims data used for this final rule with comment period revealed that the hospital resource costs for CPT codes 64613 and 64614 are significantly greater than the hospital resource costs of CPT code 64612. Therefore, we believe the proposed assignment of CPT code 64612 to APC 0204 is appropriate for CY 2009, while CPT codes 64613 and 64614 are more appropriately assigned to APC 0206.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to assign CPT code 64612 to APC 0204, with a final CY 2009 APC median cost of approximately $161.

4. Ocular Procedures

a. Suprachordial Delivery of Pharmacologic Agent (APC 0237)

In Addendum B to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66997), we assigned CPT code 0186T comment indicator ''NI'' to indicate that it was a new code for CY 2008 with an interim payment status subject to public comment following publication of that rule. In that same final rule with comment period, we also made an interim assignment of CPT code 0186T to APC 0236 (Level II Posterior Segment Eye Procedures), with a payment rate of approximately $1,161. CPT code 0186T was released by the AMA on July 1, 2007, and was implemented on January 1, 2008. Under the OPPS, we generally assign a new Category III CPT code to an APC if we believe that the procedure, if covered, would be appropriate for separate payment under the OPPS. A specific assignment to a clinical APC where HCPCS codes with comparable clinical and resource characteristics also reside is based on a variety of types of information including, but not limited to: advice from our medical advisors, information from specialty societies, review of resource costs for related services from historical hospital claims data, consideration of the clinical similarity of the service to existing procedures, and review of any other information available to us.

We did not receive any public comments regarding the interim assignment of CPT code 0186T to APC 0236 for CY 2008.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41472), we proposed to reassign CPT code 0186T (Suprachordial delivery of pharmacologic agent (does not include supply of medication)) to APC 0237 (Level II Posterior Segment Eye Procedures), from APC 0236, which we proposed to delete for CY 2009. As stated earlier, this CPT code was released by CPT on July 1, 2007, and implemented on January 1, 2008; therefore, we had no CY 2007 claims data for this service upon which to base our CY 2009 proposal.

We proposed to reassign CPT code 0186T to APC 0237, with a proposed CY 2009 payment rate of approximately $1,449, based upon our review and analysis of the clinical and resource costs associated with CPT code 0186T. We agreed with a presenter at the March 2008 APC Panel meeting that the most appropriate CY 2009 APC assignment for the procedure is APC 0237. The presenter indicated that CPT code 0186T is analogous to CPT code 67027 (Implantation of intravitreal drug delivery system (e.g., ganciclovir implant), includes concomitant removal of vitreous), which currently is assigned to APC 0672 (Level IV Posterior Segment Eye Procedures). Although the presenter stated that both procedures share similar clinical characteristics and resource costs, the presenter believed that CPT code 0186T would be most appropriately assigned to APC 0237 based on the procedure's estimated hospital cost. The APC Panel noted that because the CPT code is new and there are no claims data for this procedure, the APC Panel would not make a specific CY 2009 APC assignment recommendation to CMS at that time. However, the APC Panel recommended that CMS share with the APC Panel the claims data for CPT code 0186T at the first CY 2009 APC Panel meeting, and that CMS reevaluate the assignment of CPT code 0186T to APC 0236 on the basis of those data.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41472), we accepted the recommendation of the APC Panel and

stated that we would provide the initial OPPS claims data available for this CPT code, based on CY 2008 claims data, for the first CY 2009 APC Panel meeting. These data will not be available until the CY 2010 OPPS/ASC rulemaking cycle.

Comment: One commenter agreed with the proposed reassignment of CPT code 0186T to APC 0237. The commenter believed that the resource costs of the procedure reported with CPT code 0186T best matched those of the other eye procedures also assigned to APC 0237.

Response: We appreciate the commenter's support for our proposal.

We are finalizing our CY 2009 proposal, without modification, to assign CPT code 0186T to APC 0237, with a final CY 2009 APC median cost of approximately $1,442. We are accepting the APC Panel's March 2008 recommendation, and we will provide the initial OPPS claims data available for this CPT code, based on CY 2008 claims data, for the first CY 2009 APC Panel meeting.

b. Scanning Ophthalmic Imaging (APC 0230)

CPT code 0187T (Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral) was released by the AMA on July 1, 2007, and implemented on January 1, 2008. In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66997), we assigned CPT code 0187T to APC 0230 (Level I Eye Tests & Treatments) with a payment rate of approximately $38. We also assigned this CPT code comment indicator ''NI'' in Addendum B to the CY 2008 OPPS/ASC final rule with comment period to indicate that it is a new code for CY 2008 with an interim payment status subject to public comment following publication of that rule. As has been our longstanding policy, we do not respond to public comments submitted on the OPPS/ASC final rule with comment period regarding these interim assignments in the proposed OPPS/ASC rule for the following calendar year. However, we do review and take into consideration these public comments received during the development of the proposed rule when we evaluate APC assignments for the following year, and we respond to them in the final rule for that following calendar year.

In the CY 2009 OPPS/ASC proposed rule, we proposed to continue the assignment of CPT code 0187T to APC 0230, with a proposed payment rate of approximately $42 for CY 2009.

Comment: One commenter on the CY 2008 OPPS/ASC final rule with comment period requested that CMS reassign CPT code 0187T from APC 0230 to APC 0266 (Level II Diagnostic and Screening Ultrasound), which is the APC assigned to CPT code 76513 (Ophthalmic ultrasound, diagnostic; anterior segment ultrasound, immersion (water bath) b-scan or high resolution biomicroscopy). The commenter indicated that CPT code 76513 is very similar to CPT code 0187T because both procedures require imaging of the anterior segment of the eye, use similar resources, and utilize the same level of technical expertise in performing the procedures. However, the commenter cited a difference between the two procedures regarding how images are acquired. Specifically, the commenter explained that CPT code 0187T generates images based on light, whereas CPT code 76513 generates images by ultrasound.

Response: Based on our review of the clinical characteristics of the procedure and its expected resource costs, we continue to believe that APC 0230 is the most appropriate assignment for CPT code 0187T. We will reevaluate this APC assignment for future OPPS updates as additional information becomes available to us. We expect claims data for CPT code 0187T to be first available for the CY 2010 OPPS/ASC rulemaking cycle.

We did not receive any public comments on our proposal to continue to assign CPT code 0187T to APC 0230 for CY 2009. Therefore, we are finalizing our CY 2009 proposal, without modification, to assign CPT code 0187 to APC 0230, with a final CY 2009 APC median cost of approximately $42.

5. Orthopedic Procedures

a. Closed Treatment of Fracture of Finger/Toe/Trunk (APCs 0129, 0138, and 0139)

We received a comment in response to the CY 2008 OPPS/ASC proposed rule on the variety of procedures assigned to APC 0043 (Closed Treatment Fracture Finger/Toe/Trunk). The commenter did not agree with the placement of various procedures in APC 0043 because many of the procedures vary in resource costs. In particular, the commenter asserted that the costs associated with finger treatments, hip dislocations, and spinal fractures vary significantly, and further stated that the costs of treating spinal fractures are significantly greater than the costs associated with finger or toe fractures. The commenter also expressed concern that grouping all of the approximately 150 procedures in one clinical APC violated the 2 times rule, and that continuing to exempt APC 0043 from the 2 times rule was not appropriate. The commenter recommended that CMS pay appropriately for these procedures, and stated that this could be achieved by dividing the procedures currently assigned to APC 0043 into several APCs. However, the commenter did not make any specific recommendations regarding alternative APC configurations. Because APC 0043 contains so many different fracture treatment procedures with low volume, we were concerned that any restructuring without the benefit of public comment for CY 2008 could result in a reconfiguration of APC 0043 that did not reflect improved clinical and resource homogeneity. Therefore, we did not reconfigure APC 0043 for CY 2008, and we finalized a payment rate for APC 0043 of approximately $113.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66723), we stated that we agreed with the commenter that grouping all of the closed fracture treatment procedures in one APC may not accurately distinguish the more expensive from the less resource-intensive fracture treatment procedures. We also explained that that there were only 13 procedures with the frequency necessary to assess the APC's alignment with the 2 times rule. The other procedures were all very low volume and, therefore, not significant procedures for purposes of evaluating the APC with respect to the 2 times rule. We noted that APC 0043 had been exempted from the 2 times rule for the past 7 years under the OPPS, and we had not previously received public comments regarding the structure of this APC. We also stated that we would bring this APC issue to the attention of the APC Panel at its March 2008 meeting, and we specifically invited public recommendations on potential alternative APC configurations for the services assigned to APC 0043 for consideration for the CY 2009 OPPS rulemaking cycle. We did not receive any public comments on this APC issue in response to the CY 2008 OPPS/ASC final rule with comment period.

Based on the updated CY 2007 hospital outpatient claims data available for the March 2008 APC Panel meeting, we presented a possible reconfiguration of APC 0043 for the APC Panel's consideration that would delete APC 0043 and replace it with three new APCs, configured based on the hospital resource data from the CY 2007 claims data, as well as the clinical characteristics of the procedures currently assigned to APC 0043. The APC Panel recommended that CMS

adopt this approach, and we accepted the APC Panel's recommendation for CY 2009. Therefore, in the CY 2009 OPPS/ASC proposed rule (73 FR 41472), we proposed three new APCs to replace APC 0043, with proposed configurations as displayed in Table 15 of the proposed rule for CY 2009.

Based on these configurations, proposed new APC 0129 (Level I Closed Treatment Fracture Finger/Toe/Trunk) had a proposed APC median cost of approximately $104, with the HCPCS code-specific median costs of the significant procedures ranging from approximately $74 to $124. Proposed new APC 0138 (Level II Closed Treatment Fracture Finger/Toe/Trunk) had a proposed APC median cost of approximately $397, with one significant procedure with a HCPCS code-specific median cost of approximately $399. Proposed new APC 0139 (Level III Closed Treatment Fracture Finger/Toe/Trunk) had a proposed APC median cost of approximately $1,340, with one significant volume HCPCS code whose median cost was approximately $1,574.

We further stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41473) that while all three proposed APCs contained many procedures that were very low in volume, this reconfiguration reflected an attempt to realign the procedures previously assigned to APC 0043 into more homogeneous APC groups based on their clinical characteristics and resource costs. Therefore, in the CY 2009 OPPS/ASC proposed rule, we proposed to reconfigure APC 0043 by deleting APC 0043 and reassigning the HCPCS codes previously assigned to APC 0043 to proposed new APCs 0129, 0138, and 0139.

Comment: Several commenters commended CMS for reconfiguring APC 0043 into the proposed three new APCs 0129, 0138, and 0139.

Response: We appreciate the commenters' support for our proposal.

For this final rule with comment period, we analyzed our CY 2007 claims data used for CY 2009 OPPS ratesetting, and determined that the final median costs for proposed new APCs 0129, 0138, and 0139 are relatively similar to those for the CY 2009 OPPS/ASC proposed rule. Specifically, APC 0129 has a final APC median cost of approximately $103, with the HCPCS code-specific median costs of the significant procedures ranging from approximately $68 to $123, compared to a proposed APC median cost of approximately $104. APC 0138 has a final APC median cost of approximately $397, with one significant procedure with a HCPCS code-specific median cost of approximately $396, compared to a proposed APC median cost of approximately $397. Finally, APC 0139 has a final APC median cost of about $1,283, with one significant volume HCPCS code whose median cost is approximately $1,393, compared to a proposed APC median cost of approximately $1,340.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to delete APC 0043 and reassign the HCPCS codes previously assigned to APC 0043 to new APCs 0129, 0138, and 0139, with final CY 2009 APC median costs of approximately $103, $397, and $1,283, respectively.

TABLE 17—FINAL APCS FOR CLOSED TREATMENT FRACTURE OF FINGER/TOE/TRUNK

CY 2009 HCPCS code	Final CY 2009 SI	CY 2009 short descriptor	Final CY 2009 approximate APC median cost	Final CY 2009 APC
21800	T	Treatment of rib fracture	$103	0129
21820	T	Treat sternum fracture		
22305	T	Treat spine process fracture		
23500	T	Treat clavicle fracture		
23540	T	Treat clavicle dislocation		
23570	T	Treat shoulder blade fx		
23600	T	Treat humerus fracture		
23620	T	Treat humerus fracture		
23650	T	Treat shoulder dislocation		
23675	T	Treat dislocation/fracture		
23929	T	Shoulder surgery procedure		
24500	T	Treat humerus fracture		
24505	T	Treat humerus fracture		
24530	T	Treat humerus fracture		
24560	T	Treat humerus fracture		
24565	T	Treat humerus fracture		
24576	T	Treat humerus fracture		
24600	T	Treat elbow dislocation		
24640	T	Treat elbow dislocation		
24650	T	Treat radius fracture		
24670	T	Treat ulnar fracture		
24675	T	Treat ulnar fracture		
24999	T	Upper arm/elbow surgery		
25500	T	Treat fracture of radius		
25530	T	Treat fracture of ulna		
25535	T	Treat fracture of ulna		
25560	T	Treat fracture radius & ulna		
25600	T	Treat fracture radius/ulna		
25622	T	Treat wrist bone fracture		
25630	T	Treat wrist bone fracture		
25650	T	Treat wrist bone fracture		
25660	T	Treat wrist dislocation		
25675	T	Treat wrist dislocation		
25680	T	Treat wrist fracture		
25999	T	Forearm or wrist surgery		

TABLE 17—FINAL APCS FOR CLOSED TREATMENT FRACTURE OF FINGER/TOE/TRUNK—Continued

CY 2009 HCPCS code	Final CY 2009 SI	CY 2009 short descriptor	Final CY 2009 approximate APC median cost	Final CY 2009 APC
26600	T	Treat metacarpal fracture		
26605	T	Treat metacarpal fracture		
26641	T	Treat thumb dislocation		
26670	T	Treat hand dislocation		
26700	T	Treat knuckle dislocation		
26705	T	Treat knuckle dislocation		
26720	T	Treat finger fracture, each		
26725	T	Treat finger fracture, each		
26740	T	Treat finger fracture, each		
26742	T	Treat finger fracture, each		
26750	T	Treat finger fracture, each		
26755	T	Treat finger fracture, each		
26770	T	Treat finger dislocation		
26989	T	Hand/finger surgery		
27193	T	Treat pelvic ring fracture		
27200	T	Treat tail bone fracture		
27220	T	Treat hip socket fracture		
27230	T	Treat thigh fracture		
27250	T	Treat hip dislocation		
27256	T	Treat hip dislocation		
27265	T	Treat hip dislocation		
27267	T	Cltx thigh fx		
27299	T	Pelvis/hip joint surgery		
27501	T	Treatment of thigh fracture		
27503	T	Treatment of thigh fracture		
27508	T	Treatment of thigh fracture		
27516	T	Treat thigh fx growth plate		
27517	T	Treat thigh fx growth plate		
27520	T	Treat kneecap fracture		
27530	T	Treat knee fracture		
27538	T	Treat knee fracture(s)		
27550	T	Treat knee dislocation		
27560	T	Treat kneecap dislocation		
27599	T	Leg surgery procedure		
27750	T	Treatment of tibia fracture		
27760	T	Cltx medial ankle fx		
27767	T	Cltx post ankle fx		
27768	T	Cltx post ankle fx w/mnpj		
27780	T	Treatment of fibula fracture		
27786	T	Treatment of ankle fracture		
27788	T	Treatment of ankle fracture		
27808	T	Treatment of ankle fracture		
27816	T	Treatment of ankle fracture		
27824	T	Treat lower leg fracture		
27830	T	Treat lower leg dislocation		
27899	T	Leg/ankle surgery procedure		
28400	T	Treatment of heel fracture		
28430	T	Treatment of ankle fracture		
28435	T	Treatment of ankle fracture		
28450	T	Treat midfoot fracture, each		
28455	T	Treat midfoot fracture, each		
28470	T	Treat metatarsal fracture		
28475	T	Treat metatarsal fracture		
28490	T	Treat big toe fracture		
28495	T	Treat big toe fracture		
28510	T	Treatment of toe fracture		
28515	T	Treatment of toe fracture		
28530	T	Treat sesamoid bone fracture		
28540	T	Treat foot dislocation		
28600	T	Treat foot dislocation		
28605	T	Treat foot dislocation		
28630	T	Treat toe dislocation		
28660	T	Treat toe dislocation		
28899	T	Foot/toes surgery procedure		
20660	T	Apply, rem fixation device	$397	0138
22310	T	Treat spine fracture		
23520	T	Treat clavicle dislocation		
23525	T	Treat clavicle dislocation		
23545	T	Treat clavicle dislocation		

TABLE 17—FINAL APCS FOR CLOSED TREATMENT FRACTURE OF FINGER/TOE/TRUNK—Continued

CY 2009 HCPCS code	Final CY 2009 SI	CY 2009 short descriptor	Final CY 2009 approximate APC median cost	Final CY 2009 APC
23575	T	Treat shoulder blade fx		
23665	T	Treat dislocation/fracture		
24535	T	Treat humerus fracture		
24577	T	Treat humerus fracture		
24655	T	Treat radius fracture		
25505	T	Treat fracture of radius		
25520	T	Treat fracture of radius		
25565	T	Treat fracture radius & ulna		
25605	T	Treat fracture radius/ulna		
25624	T	Treat wrist bone fracture		
25635	T	Treat wrist bone fracture		
26340	T	Manipulate finger w/anesth		
26645	T	Treat thumb fracture		
26675	T	Treat hand dislocation		
27238	T	Treat thigh fracture		
27246	T	Treat thigh fracture		
27500	T	Treatment of thigh fracture		
27510	T	Treatment of thigh fracture		
27810	T	Treatment of ankle fracture		
27818	T	Treatment of ankle fracture		
27840	T	Treat ankle dislocation		
28570	T	Treat foot dislocation		
22315	T	Treat spine fracture	$1,283	0139
23505	T	Treat clavicle fracture		
23605	T	Treat humerus fracture		
23625	T	Treat humerus fracture		
24620	T	Treat elbow fracture		
25259	T	Manipulate wrist w/anesthes		
25690	T	Treat wrist dislocation		
26607	T	Treat metacarpal fracture		
26706	T	Pin knuckle dislocation		
27502	T	Treatment of thigh fracture		
27532	T	Treat knee fracture		
27752	T	Treatment of tibia fracture		
27762	T	Cltx med ankle fx w/mnpj		
27781	T	Treatment of fibula fracture		
27825	T	Treat lower leg fracture		
27831	T	Treat lower leg dislocation		
28405	T	Treatment of heel fracture		
28575	T	Treat foot dislocation		

b. Arthroscopic and Other Orthopedic Procedures (APCs 0041 and 0042)

For CY 2009, we proposed the following two primary APCs for arthroscopic procedures: (1) APC 0041 (Level I Arthroscopy), comprised of 44 procedures with a proposed CY 2009 payment rate of approximately $1,933; and (2) APC 0042 (Level II Arthroscopy), comprised of 30 procedures with a proposed payment rate of approximately $3,233. The CY 2008 payment rates for APCs 0041 and 0042, with the same APC configurations as proposed for CY 2009, are approximately $1,833 and $2,911, respectively.

Comment: The commenters stated that the proposed configurations of arthroscopic procedures assigned to APCs 0041 and 0042 fail to appropriately recognize the distinct clinical and resource features of the wide range of arthroscopic procedures now being provided to Medicare beneficiaries. Furthermore, they believed that there are services proposed for assignment to APC 0042 that are not arthroscopies and should be reassigned to APC 0052 (Level IV Musculoskeletal Procedure Except Hand and Foot). The commenters indicated that, as proposed, CMS data include a significant number of procedures in which the payment would be less than the median cost of the procedure. They believed that this problem was compounded by the reduced payments made for the procedures in ASCs. The commenters argued that the low level of payment for these APCs would result in barriers to high quality of care in the ASC setting. Specifically, the commenters requested that CMS reassign CPT codes 27412 (Autologous chondrocyte implantation, knee) and 27415 (Osteochondral allograft, knee, open) to APC 0052 because these are not arthroscopic procedures. They believed that these two procedures were clinically similar to procedures in APC 0052 and that their median costs were more similar to the median costs for other services in APC 0052.

The commenters further requested that CMS create 11 new arthroscopy APCs to ensure that the services within the arthroscopy APCs are clinically homogenous and contain only those procedures that are similar in terms of resource utilization. Specifically, the commenters requested that CMS restructure the arthroscopy APCs to reflect the following clinical categories: Diagnostic arthroscopies, lower extremity versus upper extremity arthroscopies without implants, and lower extremity versus upper extremity arthroscopies with implants. The

commenters believed that these clinical distinctions parallel the distinctions CMS has created for other classes of procedures, including other orthopedic procedures, and would more accurately and equitably reflect the clinical characteristics and resource utilization of the services provided. The commenters further asked that CMS consider the new APCs with implants to be device-dependent APCs so that they may be considered to be device-intensive for ASC ratesetting purposes in order to ''pass through'' the cost of the implants in the ASC payment.

Response: As a result of the concerns raised by the commenters, we reviewed the clinical characteristics and HCPCS code-specific median costs from the CY 2007 claims data for all procedures we proposed to assign to APCs 0041, 0042, and 0052 for CY 2009. Based on our findings from this review, we agree with the commenters that the procedures reported by CPT codes 27412 and 27415 are not arthroscopic procedures, that they are more clinically similar to the procedures in APC 0052, and that their median costs are better aligned with the median costs for services assigned to APC 0052. Therefore, we are reassigning CPT codes 27412 and 27415 to APC 0052 for CY 2009.

While we appreciate the commenters' suggestion that we create 11 new APCs for arthroscopic procedures, we believe that existing clinical APCs 0041 and 0042 sufficiently account for the different clinical and resource characteristics of these procedures. To reduce the size of the APC payment groups and establish new APC payment groups to pay more precisely would be inconsistent with our overall strategy to encourage hospitals to use resources more efficiently by increasing the size of the payment bundles. Moreover, many of the services that are assigned to APCs 0041 and 0042 are low volume services, with even fewer single claims available for ratesetting. Including low volume services in APCs with clinically similar higher volume services and similar median costs generates more stability in the payment rates that are set for these low volume services.

We also considered whether it would be appropriate to create two new APCs as requested by the commenters to isolate the arthroscopic procedures that the commenters indicate require implants. Our review of the CPT code definitions for the services that commenters would define as requiring implants and our understanding of the resources required to perform the procedures indicate that, for most of these procedures, implanted devices are not always required to perform the service and that in a number of cases, the ''implant'' is actually a supply or graft rather than an implantable device that would contribute to the APC's estimated device cost. Therefore, we do not believe that there is justification to create new APCs for these procedures or to designate them as device-dependent APCs. We refer readers to section XV.E.1.c. of this final rule with comment period for an explanation of the methodology used to calculate the payment rates for device-intensive procedures under the revised ASC payment system.

After consideration of the public comments received, we are finalizing our CY 2009 proposed configuration of APCs 0041 and 0042, with the modification that we are reassigning CPT codes 27412 and 27415 from APC 0042 to APC 0052. The final CY 2009 APC median costs of APCs 0041, 0042, and 0052 are approximately $1,899, $3,178, and $5,592, respectively.

c. Surgical Wrist Procedures (APCs 0053 and 0054)

For CY 2009, we proposed to retain the CY 2008 configuration of the HCPCS codes in APCs 0053 (Level I Hand Musculoskeletal Procedures) and 0054 (Level II Hand Musculoskeletal Procedures), with proposed payment rates of approximately $1,116 and $1,851, respectively. The CY 2008 payment rates for APCs 0053 and 0054, with the same APC configurations as proposed for CY 2009, are approximately $1,049 and $1,676, respectively.

Comment: One commenter asked that CMS reassign a number of CPT codes for surgical wrist procedures to alternative APCs, where they would reside with similar wrist procedures. They requested the following moves: (1) CPT code 25111 (Excision of ganglion, wrist (dorsal or volar); primary) from APC 0053 to APC 0049 (Level I Musculoskeletal Procedures Except Hand and Foot); (2) CPT code 25112 (Excision of ganglion, wrist (dorsal or volar); recurrent) from APC 0053 to APC 0049; (3) CPT code 25210 (Carpectomy; one bone) from APC 0054 to APC 0050 (Level II Musculoskeletal Procedures Except Hand and Foot); (4) CPT code 25215 (Carpectomy; all bones of proximal row) from APC 0054 to APC 0050; (5) CPT code 25394 (Osteoplasty, carpal bone, shortening) from APC 0053 to APC 0051 (Level III Musculoskeletal Procedures Except Hand and Foot); (6) CPT code 25430 (Insertion of vascular pedicle into carpal bone (eg, Hori procedure)) from APC 0054 to APC 00051; (7) CPT code 25431 (Repair of nonunion of carpal bone (excluding carpal scaphoid (navicular))(includes obtaining graft and necessary fixation), each bone) from APC 0054 to APC 0051; and (8) CPT code 25820 (Arthrodesis, wrist; limited, without bone graft (eg, intercarpal or radiocarpal) from APC 0053 to APC 0052 (Level IV Musculoskeletal Procedures Except Hand and Foot). The commenter believed that these wrist procedures typically have the same costs of personnel, supplies, and implants as the procedures assigned to the APCs in which the commenter recommended placement. Moreover, the commenter also suggested that the wrist procedures are more clinically similar to other surgical procedures already assigned to the APCs in which the commenter recommended placement.

Response: We agree with most of the commenter's recommendations and are reassigning the CPT codes to the recommended APCs for CY 2009 to improve clinical and resource homogeneity, with one exception. We do not agree that CPT code 25820 is most appropriately assigned to APC 0052. We have 123 total CY 2007 claims for this procedure, with 30 claims available for ratesetting. The median cost of the procedure is approximately $4,029, which falls between the median costs of APCs 0051 and 0052, Levels III and IV Musculoskeletal Procedures Except Hand and Foot, with APC median costs of approximately $2,929 and $5,592, respectively. Other wrist arthrodesis procedures are currently assigned to both APCs 0051 and 0052 under the OPPS, and we note that the procedure described by CPT code 25820 is a limited procedure without a bone graft, in comparison with other complete arthrodesis procedures that may utilize a graft. Therefore, based on clinical and resource considerations, we believe CPT code 25820 is most appropriately reassigned to APC 0051 for CY 2009.

After consideration of the public comments received, we are modifying our CY 2009 proposed configurations for APCs 0049, 0050, 0051, 0053, and 0054. Specifically, we are reassigning CPT codes 25111 and 25112 to APC 0049; we are reassigning CPT codes 25210 and 25215 to APC 0050; and we are reassigning CPT codes 25394, 25430, and 25431 to APC 0051 for CY 2009. We also are finalizing our CY 2009 proposal to reassign CPT code 25820 from APC 0053 to APC 0051 for the CY 2009 OPPS. The final CY 2009 median costs of APCs 0049, 0050, and 0051 are approximately $1,406, $1,929, and $2,929, respectively.

d. Intercarpal or Carpometacarpal Arthroplasty (APC 0047)

In the CY 2009 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 25447 (Arthroplasty, interposition, intercarpal or carpometacarpal joints) to APC 0047 (Arthroplasty without Prosthesis) for CY 2009, with a proposed payment rate of approximately $2,488. The CY 2008 payment rate for this procedure is approximately $2,287.

At the August 2008 APC Panel meeting, a presenter requested that the APC Panel recommend to CMS that CPT code 25447 be reassigned to APC 0048 (Level I Arthroplasty or Implantation with Prosthesis), because a costly implantable spacer device may be used when a hospital provides CPT code 25447. The presenter argued that the proposed payment rate of approximately $3,473 for APC 0048 would provide more appropriate payment for the procedure, and that the procedure clinically resembled other procedures also assigned to APC 0048. The APC Panel recommended that CMS maintain the assignment of CPT code 25447 in APC 0047 for CY 2009.

The procedure described by APC code 25447 does not always utilize an implantable device. We note that the median cost of CPT code 25447 is approximately $2,445 based on over 850 single claims, very close to the median cost of APC 0047 of approximately $2,443 and much lower than the median cost of APC 0048 of approximately $3,433. Therefore, we are adopting the APC Panel's recommendation for CY 2009.

We did not receive any public comments regarding our proposal. Therefore, we are finalizing our CY 2009 proposal, without modification, to assign CPT code 25447 to APC 0047, with a final CY 2009 APC median cost of approximately $2,443.

e. Insertion of Posterior Spinous Process Distraction Device (APC 0052)

In the CY 2009 OPPS/ASC proposed rule, we proposed to reassign CPT codes 0171T (Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar, single level) and 0172T (Insertion of posterior spinous process distraction device (including necessary removal of bone or ligament for insertion and imaging guidance), lumbar, each additional level) from APC 0050 (Level II Musculoskeletal Procedures Except Hand and Foot) to APC 0052 (Level IV Musculoskeletal Procedures Except Hand and Foot), with a proposed payment rate of approximately $5,615. The CY 2008 payment rate for APC 0050 is approximately $1,859. For CY 2007 and CY 2008, the device HCPCS code C1821 (Interspinous process distraction device (implantable)), used with CPT codes 0171T and 0172T, was assigned pass-through payment status and, therefore, was paid separately at charges adjusted to cost. As we discuss in section IV.A. of this final rule with comment period, the period of pass-through payment for HCPCS code C1821 expires after December 31, 2008. According to our usual methodology, the costs of devices no longer eligible for pass-through payments are packaged into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates for those procedures.

Comment: One commenter asserted that the proposed reassignment of CPT codes 0171T and 0172T to APC 0052 was not appropriate for a number of reasons. The commenter stated that the proposed median costs of CPT codes 0171T and 0172T of approximately $8,080 and $11,114, respectively, were substantially higher than the proposed median cost of APC 0052 of approximately $5,606. The commenter indicated that the median cost for the device HCPCS code C1821 that is always required for the procedures was $6,483, higher than the median cost of the APC to which the procedures were proposed for assignment. The commenter believed that the assignment of the procedures to APC 0052 would result in significant underpayment to hospitals and possibly limit patient access to this technology. The commenter also claimed that the assignment of CPT codes 0171T and 0172T to APC 0052 would violate the 2 times rule. The commenter recommended either the assignment of CPT codes 0171T and 0172T to a newly created clinical APC, or the reassignment of CPT codes 0171T and 0172T to APC 0425 (Level II Arthroplasty or Implantation with Prosthesis), based on clinical and resource homogeneity and device-dependent status. The commenter pointed out that the proposed rule median cost of APC 0425 of approximately $7,905 was similar to the proposed rule median costs of CPT codes 0171T and 0172T. Finally, the commenter recommended that CMS add interspinous process distraction device procedures described by CPT 0171T and 0172T to the device-to-procedure and procedure-to-device claims processing edits to ensure that future claims are correctly coded, leading to more accurate and appropriate payment policies for the technology.

Response. We continue to believe that APC 0052 is an appropriate APC assignment for CPT codes 0171T and 0172T based on consideration of the procedures' clinical and resource characteristics. The CY 2007 claims data for C1821 used for this final rule with comment period show that the interspinous process distraction device that is used with CPT codes 0171T and 0172T has a line-item median cost of approximately $4,374, whereas the median cost of APC 0052 is significantly higher, at approximately $5,592.

The HCPCS code-specific final median costs of CPT codes 0171T and 0172T are approximately $7,748 and $10,431, respectively. However, we note that because CPT code 0172T is a CPT add-on code for an additional level that should always be reported in conjunction with CPT code 0171T, the 5 single claims (out of 576 total claims) upon which the median cost of CPT code 0172T is based are likely incorrectly coded claims and, therefore, the median cost does not provide a valid estimate of the hospital resources required to perform CPT code 0172T. The median cost of CPT code 0171T of approximately $7,748 is the highest cost of the significant procedures (frequency of greater than 1,000 single claims or frequency of greater than 99 and more than 2 percent of the single claims in the APC) assigned to APC 0052, while the lowest cost significant procedure has a median cost of approximately $4,336. Therefore, the configuration of APC 0052 does not violate the 2 times rule. We continue to believe that, based on resource considerations, APC 0052 would provide appropriate payment for CPT codes 0171T and 0172T in CY 2009.

Moreover, we note that there are several other spinal procedures that require the use of implantable devices that are also assigned to APC 0052, such as the percutaneous kyphoplasty procedures described by CPT code 22523 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); thoracic) and CPT code 22524 (Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); lumbar). Therefore, we believe that CPT codes 0171T and 0172

share sufficient clinical similarity with other surgical procedures assigned to APC 0052 to justify their reassignment to APC 0052 for CY 2009.

Regarding the commenter's request that we implement device edits for interspinous process distraction device procedures, we note that we typically do not implement procedure-to-device edits where there are not device HCPCS codes for all possible devices that could be used to perform a procedure that always requires a device, and the APC is not designated as a device-dependent APC. APC 0052 is not a device-dependent APC because a number of the procedures assigned to the APC do not require the use of implantable devices. Furthermore, in some cases there may not be HCPCS codes that describe all devices that may be used to perform the procedures in APC 0052. We recognize the additional burden claims processing edits, particularly for the device-to-procedure edits, pose for hospitals, and as a result we try to limit edits only to those device and procedure combinations for which we believe costs have not been correctly captured on hospital claims. Hospitals had every incentive to report and charge for interspinous process distraction devices described by HCPCS code C1821 due to their separately payable pass-through status in CY 2007, and we have no reason to believe hospitals have not been reporting the associated implantation procedure codes along with HCPCS code C1821. Accordingly, we believe that the packaged costs of interspinous process distraction devices are appropriately reflected in the median costs of their associated implantation procedures, and that device-to-procedure edits would pose an unnecessary burden on hospitals.

After consideration of the public comment received, we are finalizing our proposed CY 2009 assignment, without modification, of CPT codes 0171T and 0172T to APC 0052, with a final CY 2009 APC median cost of approximately $5,592.

6. Radiation Therapy Services

a. Proton Beam Therapy (APCs 0664 and 0667)

For CY 2009, we proposed to pay for the following four CPT codes for proton beam therapy: 77520 (Proton treatment delivery; simple, without compensation); 77522 (Proton treatment delivery; simple, with compensation); 77523 (Proton treatment delivery; intermediate); and 77525 (Proton treatment delivery; complex). We proposed to continue to assign the simple proton beam therapy procedures (CPT codes 77520 and 77522) to APC 0664 (Level I Proton Beam Radiation Therapy), with a proposed payment rate of approximately $925, and the intermediate and complex proton beam therapy procedures (CPT codes 77523 and 77525, respectively) to APC 0667 (Level II Proton Beam Radiation Therapy), with a proposed payment rate of approximately $1,105. The CY 2008 payment rates for these APCs are approximately $817 and $977, respectively.

Comment: Several commenters supported the proposed OPPS payment rates for APCs 0664 and 0667. They indicated that proton beam therapy has numerous advantages to patients and that the proposed OPPS payment rates would pay appropriately for these services.

Response: As we proposed, we are basing the final rule payment rates for proton beam therapy and all other services paid under the OPPS on the median costs we calculated using the most current claims and cost report data that are available to us. Therefore, for CY 2009, we are setting the payment rate for proton beam therapy based on median costs of approximately $688 for APC 0664 and approximately $822 for APC 0667. These median costs result in modest declines in the final CY 2009 payment rates for proton beam therapy compared to the CY 2008 payment rates, rather than the modest increases that were proposed.

We explored our claims and cost report data to determine the reason for the change in the median costs between the proposed rule and final rule data. We found that there were two providers that billed Medicare in CY 2007 for these services. At the time we calculated the proposed rule median costs and payment rates, we used the most current claims and cost reports submitted by these hospitals. When we examined the final rule data for these hospitals, we found that both providers had submitted new cost reports subsequent to the development of the proposed rule data. The CCR from the new cost report for the provider supplying the majority of service volume in both APCs declined by more than 25 percent compared to the CCR calculated from the cost report used to determine the proposed rule costs for that provider. Therefore, the charges and costs from this provider significantly influenced the median costs for these APCs. In summary, the estimated costs of proton beam therapy services decreased because the most current CCRs, which declined compared to the CCRs used to calculate the proposed rule costs, were applied to charges that remained consistent from the proposed rule to the final rule claims. Our examination of the claims and cost report data showed no characteristics that would cause us to believe that the estimated costs for this final rule with comment period are inappropriate for the services furnished.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to pay for proton beam therapy through APCs 0664 and 0667, with payment rates based upon the most current claims and cost report data for these services. The final CY 2009 APC median costs of APCs 0664 and 0667 are approximately $688 and $822, respectively.

b. Implantation of Interstitial Devices (APC 0310)

In the CY 2009 OPPS/ASC proposed rule, we proposed to reassign CPT code 55876 (Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple) to APC 0310 (Level III Therapeutic Radiation Treatment Preparation) with a proposed payment rate of approximately $901, based on our review of CY 2007 claims data for the service and consideration of the service's clinical characteristics. For CY 2008, CPT code 55876 is assigned to APC 0156 (Level III Urinary and Anal Procedures), with a payment rate of approximately $194.

Comment: One commenter supported the proposed reassignment of CPT code 55876 to APC 0310, with the proposed increase in payment for the service.

Response: We appreciate the commenter's support and are finalizing, without modification, our CY 2009 proposal to reassign CPT code 55876 to APC 0310, with a final CY 2009 APC median cost of approximately $873.

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

In the CY 2009 OPPS/ASC proposed rule, we proposed to continue to assign SRS CPT codes 77372 (Radiation treatment delivery, stereotactic radiosurgery (SRS) (complete course of treatment of cerebral lesion(s) consisting of 1 session); linear accelerator based) and 77373 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions) status indicator ''B'' under the OPPS, to indicate that these CPT codes are not payable under the OPPS. Alternatively, we proposed to continue to recognize for separate payment the HCPCS G-codes that describe SRS

treatment delivery services. Specifically, we proposed the following: to assign HCPCS code G0173 (Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session) to APC 0067 (Level III Stereotactic Radiosurgery, MRgFUS, and MEG), with a proposed payment rate of approximately $3,664; to assign HCPCS code G0251 (Linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment) to APC 0065 (Level I Stereotactic Radiosurgery, MRgFUS, and MEG), with a proposed payment rate of approximately $995; to assign HCPCS code G0339 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment) to APC 0067, with a proposed payment rate of approximately $3,664; and to assign HCPCS code G0340 (Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment) to APC 0066 (Level II Stereotactic Radiosurgery, MRgFUS, and MEG), with a proposed payment rate of approximately $2,654.

Comment: Several commenters urged CMS to recognize CPT codes 77372 and 77373 under the OPPS rather than continuing to use the Level II HCPCS G-codes for SRS treatment delivery services. One commenter requested that CMS recognize the CPT codes to facilitate claims processing by non-Medicare payers who do not accept temporary HCPCS codes in their claims processing systems. Another commenter suggested that CMS recognize the SRS treatment delivery CPT codes for separate payment under the OPPS, and provide payment through one clinical APC. The commenter argued that this change would reduce the number of APCs for SRS treatment delivery services and provide more clarity to hospitals.

Response: As we explained in both the CY 2007 OPPS/ASC final rule with comment period (71 FR 68025–68026) and the CY 2008 OPPS/ASC final rule with comment period (72 FR 66734 through 66737), we decided to recognize the Level II HCPCS codes, specifically HCPCS codes G0251 and G0340, because they are more specific in their descriptors than the CPT codes for SRS treatment delivery services. In the CY 2004 OPPS final rule with comment period (68 FR 63431) and in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66735), we also explained the basis for creating the Level II HCPCS codes. We continue to believe that the Level II HCPCS codes are more specific in their descriptors and more accurately reflect the SRS treatment delivery services provided in the hospital outpatient setting than the CPT codes for SRS treatment delivery services.

Analysis of the CY 2007 claims data used for this final rule with comment period indicate that the HCPCS code-specific median cost is approximately $931 for HCPCS code G0251; approximately $2,522 for HCPCS code G0340; approximately $3,523 for HCPCS code G0173; and approximately $3,718 for HCPCS code G0339. Because the CY 2009 median costs of HCPCS codes G0173, G0251, G0339, and G0340 vary significantly, we do not believe it would be appropriate to provide OPPS payment through a single APC for these SRS treatment delivery services in CY 2009. Furthermore, we have no way of crosswalking hospital costs for the HCPCS G-codes to the expected costs for the SRS CPT codes that would ensure continued accurate payment for SRS treatment delivery services under the OPPS if we were to recognize the CPT codes. Depending on the individual clinical case, the SRS treatment delivery services described by a single CPT code could be reported by one of several of the HCPCS G-codes and, similarly, the SRS treatment delivery services currently described by a single HCPCS G-code could be reported by one of several CPT codes.

Hospitals have told us that many other payers recognize Level II HCPCS codes for payment, although each payer may set its own reporting guidelines. With respect to the identification of HCPCS codes for services under the OPPS, we recognize those codes that lead to the most appropriate payment for services under the OPPS, using CPT codes whenever we believe their recognition leads to accurate payment. Otherwise, we may determine that Level II HCPCS codes should be used for reporting OPPS services, as is the case for SRS services.

Comment: Some commenters expressed concern about the difference in the proposed payment rate of approximately $995 for HCPCS code G0251 and that of approximately $2,654 for HCPCS code G0340. The commenters found no clinical justification for the differential payment for these services. They believed that one technology should not be favored over another when both technologies provide similar radiation dose distribution and clinical outcomes. The commenters recommended that CMS recognize CPT codes 77372 and 77373 rather than use HCPCS codes G0251 and G0340, and set the payment rate to be the same for both CPT codes. Another commenter requested that CMS continue to recognize the four HCPCS G-codes for SRS treatment delivery services and finalize their proposed assignments to their respective clinical APCs for CY 2009.

Response: As we have stated previously, we believe that HCPCS codes G0251 and G0340 are more specific in their descriptors for SRS treatment delivery services than CPT codes 77372 and 77373, and therefore, we will continue to recognize the Level II HCPCS codes for SRS treatment delivery services under the OPPS.

Based on our review of the CY 2007 claims data used for this final rule with comment period, we found that the costs of HCPCS codes G0251 and G0340 differ significantly. Specifically, our CY 2007 claims data showed 10,022 single claims for HCPCS G0340, with a HCPCS code-specific median cost of approximately $2,522, whereas the median cost for HCPCS code G0251 based on 3,132 single claims is only approximately $931. Our CY 2007 claims data used for this final rule with comment period do not support a single payment for both services as suggested by some commenters, and as a result, we find no justification for setting the same payment rate for the CPT codes that would describe some of the services currently reported with HCPCS codes G025 and G0340.

Moreover, we note that there are two additional Level II HCPCS codes for SRS treatment delivery services that are recognized for payment under the OPPS, specifically HCPCS codes G0173 and G0339, that describe services that could be reported under CPT code 77372 or 77373. These HCPCS G-codes also have median costs of approximately $3,523 and $3,718, respectively, significantly different from the median costs of HCPCS codes G0251 and G0340 and, therefore, we proposed to assign HCPCS codes G0173 and G0339 to a third clinical APC, that is APC 0067. We continue to believe that all four HCPCS G-codes for SRS treatment delivery services are most appropriately assigned to the three APCs in the Stereotactic Radiosurgery, MRgFUS, and MEG clinical series, where they are paid based on APC median costs that are consistent with their HCPCS code-specific median costs that reflect required hospital resources.

After consideration of the public comments received, we are finalizing

our CY 2009 proposal, without modification, to continue to recognize Level II HCPCS codes G0251 and G0340, instead of CPT codes 77372 and 77373, for the reporting of SRS treatment delivery services under the OPPS in CY 2009. For CY 2009, HCPCS code G0251 is assigned to APC 0065 with a final APC median cost of approximately $931, and HCPCS code G0340 is assigned to APC 0066 with a final APC median cost of approximately $2,522. We also are finalizing our CY 2009 proposal to continue to recognize HCPCS codes G0173 and G0339, assigned to APC 0067 with a final median cost of approximately $3,718, for certain SRS services reported in accordance with the codes descriptors of these two HCPCS G-codes.

In addition, for CY 2009, the CPT Editorial Panel decided to delete CPT code 61793 (Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator), one or more sessions) on December 31, 2008, and replace it with several new CPT codes, specifically CPT codes 61796, 61797, 61798, 61799, 61800, 63620, and 63621, effective January 1, 2009. Similar to its predecessor code, all of the replacement codes have been assigned status indicator ''B'' on an interim basis under the OPPS because we are continuing to recognize the HCPCS G-codes for SRS treatment delivery services under the OPPS in CY 2009. In accordance with our established policy for the treatment of new CPT codes under the OPPS, we also have assigned these replacement codes comment indicator ''NI'' in Addendum B to this final rule with comment period to indicate that these new CPT codes are open to public comment in this final rule with comment period. The replacement codes for CPT code 61793 are displayed in Table 18 below.

TABLE 18—REPLACEMENT CODES FOR CPT CODE 61793 EFFECTIVE JANUARY 1, 2009

CY 2009 HCPCS code	CY 2009 long descriptor	CY 2009 interim SI
61796	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion.	B
61797	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); each additional cranial lesion, simple.	B
61798	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); 1 complex cranial lesion.	B
61799	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); each additional cranial lesion, complex.	B
61800	Application of stereotactic headframe for stereotactic radiosurgery	B
63620	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 spinal lesion.	B
63621	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); each additional spinal lesion.	B

7. Other Procedures and Services

a. Negative Pressure Wound Therapy (APC 0013)

In the CY 2009 OPPS/ASC proposed rule, we proposed to assign CPT codes 97605 (Negative pressure wound therapy (e.g., vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters) and 97606 (Negative pressure wound therapy (e.g., vacuum assisted drainage collection), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters) to APC 0013 (Level II Debridement and Destruction) for CY 2009, with a proposed payment rate of approximately $55. For CY 2008, CPT code 97605 is also assigned to APC 0013, with a payment rate of approximately $51, but CPT code 97606 is assigned to APC 0015 (Level III Debridement and Destruction), with a payment rate of approximately $93. We proposed to reassign CPT code 97606 from APC 0015 to APC 0013 for CY 2009 because its median cost of $75, based on the CY 2007 proposed rule claims data, indicated that the resource costs associated with this procedure were more similar to the resource costs of the procedures assigned to APC 0013 than the procedures assigned to APC 0015.

Comment: One commenter requested that CMS maintain the CY 2008 payment rates for CPT codes 97605 and 97606 in CY 2009 and noted that negative pressure wound therapy often requires greater time and resources than reflected in the proposed payment rate for CPT code 97606. The commenter claimed that these codes are used to report negative pressure wound therapy for increasingly more complicated wounds. The commenter also requested that CMS refer both codes to the CPT Wound Care Workgroup for development of new code descriptors.

Response: As a result of the concerns raised by the commenter, we reviewed the clinical characteristics and HCPCS code-specific median costs from our CY 2007 claims data for all procedures we proposed to assign to APCs 0013 and 0015 for CY 2009. Based on the resource costs associated with these codes, as reported by hospitals, we continue to believe that APC 0013 is the most appropriate assignment for CPT codes 97605 and 97606. The median costs of these two services are approximately $64 and $74, respectively, based on thousands of single claims available for ratesetting. These median costs fall well within the range of median costs of the other significant procedures also assigned to APC 0013, ranging from approximately $40 to $78. In contrast, the median cost of APC 0015 is significantly higher, at approximately $98, than the median costs of the negative pressure wound therapy services.

To the extent that, in the future, hospitals use these CPT codes to report more resource intensive services than are currently reflected in claims data, we would expect to see higher costs reported by hospitals in the future. We would reevaluate whether a different APC assignment was appropriate at that time. We currently do not have concerns based on historical patterns of hospital reporting and hospital costs about the CPT codes reported by hospitals for payment of negative pressure wound care services under the OPPS. We note that any interested party may refer CPT codes to the CPT Editorial Panel for reassessment.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without

modification, to assign CPT codes 97605 and 97606 to APC 0013, with a final CY 2009 APC median cost of approximately $53.

b. Endovenous Ablation (APCs 0091 and 0092)

In the CY 2009 OPPS/ASC proposed rule, we proposed to continue to assign CPT code 36475 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated) to APC 0091 (Level II Vascular Ligation) and to continue to assign CPT code 36478 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated) to APC 0092 (Level I Vascular Ligation), with proposed payment rates of approximately $2,833 and $1,781, respectively. The CY 2008 payment rate for APC 0091 is approximately $2,714, and the CY 2008 payment rate for APC 0092 is approximately $1,646.

Comment: One commenter expressed concern about decreases in the OPPS payment for outpatient medical procedures, specifically for CPT codes 36475 and 36478, while the costs of supplies and malpractice insurance and the costs of care for the uninsured have increased.

Response: We review, on an annual basis, the APC assignments and relative payment weights for services and items paid under the OPPS. Based on our findings, we propose to revise the APC assignments to account for the following factors: Changes in medical practice; changes in technology; addition of new services; new cost data; advice and recommendations from the APC Panel; and other relevant information. The OPPS is a budget neutral payment system, with payment for most individual services determined by the relative costs of the required hospital resources as determined from historical hospital costs for these services. For CY 2009, we estimate that providers overall will receive a 3.9 percent increase in aggregate payment under the OPPS, as discussed in more detail in section XXIII.B. of this final rule with comment period. We note that we proposed to increase the CY 2009 payment rates for CPT codes 36475 and 36478 by approximately 5 percent, 2 percentage points more than the proposed annual CY 2009 market basket update factor of 3 percent for the OPPS, based on the relative costs that hospitals have reported to us for these OPPS services.

Based on our latest CY 2007 claims data, we believe that CPT code 36475, with a final HCPCS code-specific median cost of approximately $2,404, is appropriately assigned to APC 0091, with a final APC median cost of approximately $2,828. Similarly, we believe that CPT code 36478, with a final HCPCS code-specific median cost of approximately $1,853, is appropriately assigned to APC 0092, with a final APC median cost of approximately $1,767. Both of these procedures are clinically similar to other procedures also assigned to their respective APCs, and they are similar in terms of hospital resources to the other procedures assigned to their respective APCs, as reflected in their median costs.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to continue assignment of CPT code 36475 to APC 0091, with a final CY 2009 APC median cost of approximately $2,828, and CPT code 36478 to APC 0092, with a final CY 2009 APC median cost of approximately $1,767.

c. Unlisted Antigen Skin Testing (APC 0341)

CPT code 86486 (Skin test; unlisted antigen, each) is a new CPT code for CY 2008. Therefore, in accordance with our established policy for the treatment of new CPT codes under the OPPS, in Addendum B to the CY 2008 OPPS/ASC final rule with comment period, we assigned CPT code 86486 an interim status indicator of ''A'' (Services furnished to a hospital outpatient that are paid under a few schedule or payment system other than OPPS). In that final rule with comment period, we also assigned CPT code 86468 comment indicator ''NI'' to indicate that its OPPS treatment as a new code was open to public comment in that rule. As stated earlier in section III.D.4.b. of this final rule with comment period and in accordance with our longstanding policy, we do not respond to public comments submitted on the OPPS/ASC final rule with comment period with respect to these interim assignments in the proposed OPPS/ASC rule for the following calendar year. However, we do review and take into consideration these public comments received during the development of the proposed rule when we evaluate APC assignments for the following year, and we respond to them in the final rule for that following calendar year.

In the CY 2009 OPPS/ASC proposed rule, we proposed to assign CPT code 86486 to APC 0341 (Skin Tests) with a status indicator of ''X'' and a proposed payment rate of approximately $6.

Comment: One commenter on the CY 2008 OPPS/ASC final rule with comment period questioned CMS's CY 2008 interim status indicator assignment of ''A'' to CPT code 86486, when all of the other CPT codes within the same clinical series were assigned status indicator ''X'' and paid separately under APC 0341. The commenter requested that CMS review the interim status indicator assignment for CPT code 86486 and analyze the code's similarity to other skin tests that are assigned to APC 0341.

Response: After reviewing the concerns raised by the commenter and the clinical and resources characteristics of CPT code 86486, we agree with the commenter that the service should be assigned to APC 0341 with a status indicator of ''X,'' and we made this proposal for CY 2009.

We did not receive any public comments regarding our CY 2009 proposal. Therefore, we are finalizing our CY 2009 proposal, without modification, to assign CPT code 86486 to APC 0341, with a final CY 2009 APC median cost of approximately $5.

d. Home International Normalized Ratio (INR) Monitoring (APC 0607)

In the CY 2009 OPPS/ASC proposed rule, we proposed to continue to assign HCPCS code G0248 (Demonstration, prior to initial use, of home INR monitoring for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria, under the direction of a physician; includes: face-to-face demonstration of use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing prior to its use) and HCPCS code G0249 ((Provision of test materials and equipment for home INR monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; not occurring more frequently than once a week) to APC 0607 (Level 4 Hospital Clinic Visits) for CY 2009, with a proposed payment rate of approximately $106. The CY 2008 payment rate for APC 0607 is approximately $104.

Comment: One commenter stated that it was reasonable for CMS to maintain assignment of these two CPT codes to APC 0607 for CY 2009. The commenter stated that this assignment continues to be reasonable insofar as the services are clinically homogeneous and the proposed payment rate, although likely

lower than the hospital costs incurred in providing these services, appears to be sufficient to allow continued monitoring of utilization and access for at least another year. While stating that utilization of home INR monitoring remains very low among Medicare beneficiaries, especially in the hospital outpatient anticoagulation clinic setting, the commenter encouraged CMS to continue to monitor these codes to ensure proper APC assignment, as coverage for these services was recently expanded beyond patients with mechanical heart valves to include Medicare patients with chronic atrial fibrillation or venous thromboembolism.

Response: We appreciate the commenter's support for our proposal. We agree that a much more substantial population of Medicare beneficiaries who undergo anticoagulation therapy may now be eligible for these services due to the recent expansion in Medicare coverage for the services reported by HCPCS codes G0248 and G0249. On an annual basis, we review the APC assignments and relative payment weights for services and items paid under the OPPS. Based on our findings, we may propose to revise the APC assignments to appropriately account for changes in medical practice or hospital costs, among other factors. We will continue to assess the most current claims data for HCPCS codes G0248 and G0249 for our future annual OPPS updates.

After consideration of the public comment received, we are finalizing our CY 2009 proposal, without modification, to continue the assignment of CPT codes G0248 and G0249 to APC 0607, with a final CY 2009 APC median cost of approximately $111.

e. Mental Health Services (APCs 0322, 0323, 0324, and 0325)

APC 0323 (Extended Individual Psychotherapy) had a 2 times rule violation for CYs 2007 and 2008, and was exempted from the 2 times rule during those years. APC 0323 would continue to have a 2 times rule violation in CY 2009 if its configuration is not adjusted. In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66739), we agreed to review APC 0323 at the next APC Panel meeting and seek the APC Panel's guidance in reconfiguring this APC for CY 2009.

It was brought to our attention that a few CPT codes describe psychotherapy services that could be appropriately provided and reported as part of a partial hospitalization program, but would not otherwise be appropriately reported by a HOPD for those psychotherapy services. Specifically, the category heading in the 2008 CPT book specifies that the CPT codes listed in Table 16 of the CY 2009 OPPS/ASC proposed rule are to be reported for services provided in an ''inpatient hospital, partial hospital, or residential care facility.'' (Table 16 is reprinted below in this final rule with comment period as Table 19.) These CPT codes have been assigned to APCs 0322 (Brief Individual Psychotherapy) and 0323 since the implementation of the OPPS.

TABLE 19—INPATIENT HOSPITAL, PARTIAL HOSPITAL, OR RESIDENTIAL CARE FACILITY PSYCHOTHERAPY CODES

CY 2009 HCPCS code	CY 2009 long descriptor
90816	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient;
90817	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services.
90818	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient;
90819	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management.
90821	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient;
90822	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services.
90823	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient;
90824	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services.
90826	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient;
90827	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services.
90828	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient;
90829	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an inpatient hospital, partial hospital or residential care setting, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services.

The 2008 CPT book also includes a parallel set of CPT codes whose category heading in the CPT book specifies that these codes are to be reported for services provided in the office or other outpatient facilities. These CPT codes were listed in Table 17 of the CY 2009 OPPS/ASC proposed rule, which is reprinted below as Table 20. These CPT codes also have been assigned to APCs 0322 and 0323 since the implementation of the OPPS.

TABLE 20—OFFICE OR OTHER OUTPATIENT FACILITY PSYCHOTHERAPY CODES

CY 2009 HCPCS code	CY 2009 long descriptor
90804	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient;
90805	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services.
90806	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient;
90807	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management.
90808	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient;
90809	Individual psychotherapy, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services.
90810	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient;
90811	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 20 to 30 minutes face-to-face with the patient; with medical evaluation and management services.
90812	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient;
90813	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 45 to 50 minutes face-to-face with the patient; with medical evaluation and management services.
90814	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient;
90815	Individual psychotherapy, interactive, using play equipment, physical devices, language interpreter, or other mechanisms of non-verbal communication, in an office or outpatient facility, approximately 75 to 80 minutes face-to-face with the patient; with medical evaluation and management services.

Our CY 2007 claims data for the CY 2009 OPPS/ASC proposed rule (excluding all claims for partial hospitalization services) included approximately 10,000 OPPS claims for CPT codes 90816 through 90829, compared with approximately 500,000 claims for CPT codes 90804 through 90815. We were unclear as to what HOPD services these claims for CPT codes 90816 through 90829 represented and believed that these may be miscoded claims. We did not believe that CPT codes 90816 through 90829 could be appropriately reported for hospital outpatient services that are not part of a partial hospitalization program. Therefore, in the CY 2009 OPPS/ASC proposed rule (73 FR 41476), we proposed to assign status indicator ''P'' to CPT codes 90816 through 90829 for CY 2009, indicating that these services may be billed appropriately and paid under the OPPS only when they are part of a partial hospitalization program. Partial hospitalization services are not included in our ratesetting process for nonpartial hospitalization OPPS services. Under this proposal, hospitals would continue to report CPT codes 90804 through 90815 for individual psychotherapy services provided in the HOPD that are not part of partial hospitalization services, consistent with CPT instructions.

For the CY 2009 OPPS/ASC proposed rule, we recalculated the median costs for APCs 0322 and 0323, after assigning status indicator ''P'' to CPT codes 90816 through 90829 (73 FR 41477). We stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41477) that, as partial hospitalization services only, the claims data for these codes would only be considered for ratesetting with respect to partial hospitalization services paid through the two proposed CY 2009 partial hospitalization APCs, specifically APC 0172 (Level I Partial Hospitalization (3 services)) and APC 0173 (Level II Partial Hospitalization (4 or more services)), and that no historical hospital claims data would continue to map to APCs 0322 and 0323. We refer readers to section X.B. of this final rule with comment period for a complete discussion of the proposed CY 2009 partial hospitalization payment policy. The CY 2009 proposed median costs for APCs 0322 and 0323 were approximately $88 and $108, respectively. This proposed new configuration for APC 0323 eliminated the longstanding 2 times violation for this APC, although the median cost remained approximately the same as it was for CYs 2007 and 2008.

During its March 2008 APC Panel meeting, the APC Panel recommended that CMS restructure APC 0323 as described above, and that a similar restructuring be considered for APC 0322. In the CY 2009 OPPS/ASC proposed rule (73 FR 41477), we stated that we were adopting the APC Panel's recommendation and, therefore, we proposed to assign status indicator ''P'' to CPT codes 90816 through 90829 for CY 2009.

Comment: Several commenters requested that CMS not assign status indicator ''P'' to CPT codes 90804 through 90815, indicating that these

services are often billed by HOPDs outside of a partial hospitalization program.

Response: We believe that commenters may have misunderstood our proposal. For CY 2009, we proposed to assign status indicator ''Q3'' rather than ''P'' to CPT codes 90804 through 90815. We proposed to assign status indicator ''P'' to CPT codes 90816 through 90829, in order that payment for CPT codes 90816 through 90829 would only be made through payment for a partial hospitalization program. We agree with the commenters that CPT codes 90804 through 90815 may be appropriately billed by HOPDs outside of a partial hospitalization program, as reflected in our CY 2009 proposal. Hospitals would continue to receive payment for CPT codes 90804 through 90815 when billed by an HOPD.

We believe that commenters may have been confused about the proposal to assign status indicator ''Q3'' to CPT codes 90804 through 90815 for CY 2009. As discussed in detail in section II.A.2.e.(4) of this final rule with comment period, for CY 2009 we proposed to change the status indicator to ''Q3'' (Codes that May be Paid Through a Composite APC), for the HCPCS codes that describe the specified mental health services to which APC 0034 (Mental Health Services Composite) applies. These codes are conditionally packaged when the sum of the payment rates for the single code APCs to which they are assigned exceeds the per diem payment rate for partial hospitalization. We proposed to apply this status indicator policy to the HCPCS codes that are assigned to composite APC 0034 in Addendum M to the proposed rule. We refer readers to section XIII.A. of this final rule with comment period for a complete discussion of status indicators and our status indicator changes for CY 2009.

Comment: Several commenters expressed concern that the payment rate for APC 0325 (Group Psychotherapy) as proposed for CY 2009 reflected a decrease of 21.62 percent from CY 2006 to CY 2009. One commenter was concerned that the payment rate would be insufficient to cover its costs for providing mental health services, especially in a geographic area designated as a Mental Health Provider Shortage Area. Another commenter asked whether the proposed APC payment rates for APCs 0322, 0323, 0324 (Family Psychotherapy), and 0325 were properly set based upon substantiated data.

Response: Unlike APCs 0322 and 0323, we did not specifically discuss APCs 0324 and 0325 in the CY 2009 OPPS/ASC proposed rule because we did not propose any significant changes to these APCs. Instead, we proposed to calculate payment rates for these APCs following our standard OPPS ratesetting methodology.

As one commenter noted, the payment rate for APC 0325 declined by 17 percent between CYs 2006 and 2007 and then declined an additional 5 percent from CY 2007 to CY 2008. The CY 2009 proposed payment rate for APC 0325 of approximately $63 represents an additional decrease of 1 percent from CY 2008. However, based upon the updated CY 2007 final rule claims data, the CY 2009 payment rate for APC 0325 is $65, very similar to the CY 2008 payment rate of approximately $63. As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66739), we cannot speculate as to why the median cost of group psychotherapy services decreased significantly between CY 2006 and CY 2008.

We note that we have robust claims data for the CPT codes that map to APC 0325. Specifically, we were able to use more than 99 percent of the approximately 1.5 million claims submitted by hospitals to report group psychotherapy services. We set the payment rates for the APCs containing psychotherapy services using our standard OPPS methodology based on relative costs from hospital outpatient claims. We have no reason to believe that our claims data, as reported by hospitals, do not accurately reflect the hospital costs of group psychotherapy services. It would appear that the relative cost of providing these mental health services in comparison with other HOPD services has decreased in recent years.

Therefore, for CY 2009, we are finalizing our CY 2009 proposed configurations for APC 0322, 0323, 0324, and 0325, without modification. In doing so, we are adopting the APC Panel recommendation to assign status indicator ''P'' to CPT codes 90816 through 90829. The final CY 2009 median costs of APCs 0322, 0323, 0324, and 0325 are approximately $85, $105, $161, and $63, respectively.

f. Trauma Response Associated With Hospital Critical Care Services (APC 0618)

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68133 through 68134), we discussed the creation of HCPCS code G0390 (Trauma response team activation associated with hospital critical care service), which became effective January 1, 2007. HCPCS code G0390 is reported by hospitals when providing critical care services in association with trauma response team activation. HCPCS code G0390 has been assigned to APC 0618 (Trauma Response with Critical Care) since CY 2007, with payment rates of approximately $495 and $330 for CYs 2007 and 2008, respectively. The creation of HCPCS code G0390 enables us to pay differentially for critical care when trauma response team activation is associated with critical care services and when there is no trauma response team activation. We instructed hospitals to continue to report CPT codes 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) and 99292 (Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)) for critical care services when they also report HCPCS code G0390.

For CYs 2007 and 2008, we calculated the median cost for APC 0617 (Critical Care) to which CPT code 99291 is assigned using the subset of single claims for CPT code 99291 that did not include charges under revenue code 068x, the trauma revenue code, reported on the same day. We established the median cost for APC 0618 by calculating the difference in median costs between the two subsets of single claims for CPT code 99291 representing the reporting of critical care services with and without revenue code 068x charges reported on the same day. For a complete description of the history of the policy and development of the payment methodology for these services, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 68133 through 68134). We provided billing guidance in CY 2006 in Transmittal 1139, Change Request 5438, issued on December 22, 2006, specifically clarifying when it would be appropriate to report HCPCS code G0390. The I/OCE logic only accepts HCPCS code G0390 when it is reported with revenue code 068x and CPT code 99291 on the same claim and on the same date of service.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41471), we proposed a median cost for APC 0617 of approximately $488 and a median cost for APC 0618 of approximately $989 for CY 2009. For the CY 2009 OPPS ratesetting, we used claims data from CY 2007 that also included claims for HCPCS code G0390, as CY 2007 is the initial year that we established OPPS payment for HCPCS code G0390. We proposed to use the line-item median cost for HCPCS code G0390 in the CY 2007 claims to set the median cost for

APC 0618, as HCPCS code G0390 is the only code assigned to that APC. As discussed in section II.A.1.b. of this final rule with comment period, we proposed to add HCPCS code G0390 to the CY 2009 bypass list to isolate the line-item cost for HCPCS code G0390 and ensure that the critical care claims for CPT code 99291 that are reported with HCPCS code G0390 are available to set the medians for APC 0617 and composite APC 8003. The costs of packaged revenue code charges and HCPCS codes for services with status indicator ''N'' on a claim with HCPCS code G0390 would be associated with CPT code 99291 for ratesetting, if the claim for CPT code 99291 is a single or ''pseudo'' single bill.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41472), we proposed to calculate the median cost for APC 0617 using our standard methodology that excludes those single claims for critical care services that are eligible for payment through the Level II extended assessment and management composite APC, that is APC 8003, as described in section II.A.2.e.(1) of this final rule with comment period for CY 2009. As indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41472), we believe that these proposed refinements in median cost calculations would result in more accurate cost estimates and payments for APCs 0617 and 0618 for CY 2009.

Comment: One commenter supported the proposed payment increase for HCPCS code G0390 from $330 in CY 2008 to $991 in CY 2009. Several commenters requested that CMS allow hospitals to report HCPCS code G0390 with CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)), in addition to CPT code 99291 (and CPT code 99292, when appropriate), and stated that when less than 30 minutes of critical care are provided to a patient, the hospital may not bill CPT code 99291 and must bill another appropriate visit code instead, often CPT code 99285.

Response: We appreciate the commenter's support for the proposed CY 2009 payment for HCPCS code G0390. As noted by commenters, when less than 30 minutes of critical care are provided, hospitals may not bill CPT code 99291, according to CPT instructions, and may instead bill an appropriate visit code. We understand that hospitals may be reporting CPT code 99285 most often when less than 30 minutes of critical care are provided. However, we continue to believe that the 068x series revenue codes used to report a trauma response are most often reported with CPT code 99291, rather than other visit codes, and are most appropriately paid separately only under the circumstances that a Medicare beneficiary receives a significant period of critical care in the HOPD.

If less than 30 minutes of critical care are provided, the payment for trauma response is packaged into payment for the visit code or other services provided to the patient. We note that the cost of trauma response will generally be reflected in the median cost for the visit code or other HCPCS code as a function of the frequency of the reporting of trauma response charges with the particular separately payable HCPCS code. Consistent with the principles of a prospective payment system, OPPS payment may be more or less than the estimated costs of providing a service or package of services for a particular patient, but with the exception of outlier cases, is adequate to ensure access to appropriate care. Hospitals that bill a visit code or other services, as well as a charge for trauma response, may be eligible for outlier payment, if their costs meet the outlier threshold.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to pay separately for HCPCS code G0390 when billed with CPT code 99291, and to provide payment for HCPCS code G0390 through APC 0618, with a final CY 2009 APC median cost of approximately $914. We are also finalizing, without modification, our CY 2009 proposal to calculate the median cost for HCPCS code G0390 using our standard methodology that excludes those single claims for critical care services that are eligible for payment through the Level II extended assessment and management composite APC 8003.

IV. OPPS Payment for Devices

A. Pass-Through Payments for Devices

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

a. Background

Section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3, years. This period begins with the first date on which transitional pass-through payments are eligible 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 expiration dates for the category codes on the date on which a category was first eligible for pass-through payment. We propose and finalize the dates for expiration of pass-through payments for device categories as part of the OPPS annual update.

Two currently eligible categories, HCPCS code C1821 (Interspinous process distraction device (implantable)) and HCPCS code L8690 (Auditory osseointegrated device, includes all internal and external components), were established for pass-through payment as of January 1, 2007. These two device categories will be eligible for pass-through payment for 2 years through December 31, 2008. In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66751), we finalized our policy to expire these two categories from pass-through device payment after December 31, 2008.

We also have an established policy to package the costs of the devices 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.

b. Final Policy

In the CY 2009 OPPS/ASC proposed rule (73 FR 41477), we stated that we are implementing the final decisions that we discussed in the CY 2008 OPPS/ASC final rule with comment period that finalize the expiration date of pass-through status for device categories described by HCPCS codes C1821 and L8690. We did not receive any public comments on our statement of these decisions on expiration of the HCPCS codes L8690 and C1821 categories. Responses to public comments regarding the proposed CY 2009 APC assignments for surgical procedures associated with HCPCS codes L8690 and C1821 and into which payment for these devices is packaged for CY 2009, are included in sections II.A.2.d.(1) and III.D.5.e. of this final rule with comment period, respectively. Therefore, as of January 1, 2009, we will discontinue pass-through payment for HCPCS device category codes C1821 and L8690. In accordance with our established policy, we will package the costs of the devices assigned to these two device categories into the costs of the procedures with which the devices were billed in CY 2007, the year of hospital claims data used for this CY 2009 OPPS update.

We currently have no established device categories eligible for pass-through payment that are continuing into CY 2009. We continue to evaluate

applications for pass-through payment of medical devices on an ongoing basis. We may establish a new device category in any quarter, and we will advise the public of our decision to establish a new device category in a subsequent quarter in CY 2009 through the transmittal that implements the OPPS update for the applicable quarter. We would then propose an expiration date for such new categories in future OPPS annual updates.

2. 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 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 APC offset amounts for eligible pass-through device categories through the transmittals that implement the quarterly OPPS updates.

b. Final Policy

In the CY 2009 OPPS/ASC proposed rule (73 FR 41478), we proposed to continue our established policies for calculating and setting the APC offset amounts for each device category eligible for pass-through payment. We also proposed to continue to review each new device category on a case-by-case basis, to determine whether device costs associated with the new category are already packaged into the existing APC structure. If device costs packaged into the existing APC structure are associated with the new category, we would deduct the APC offset amount from the pass-through payment for the device category.

We did not receive any public comments regarding these proposals. Therefore, for CY 2009, we are continuing our established policies for calculating and setting the APC offset amounts for each device category eligible for pass-through payment, and for reviewing each new device category on a case-by-case basis, to determine whether device costs associated with the new category are packaged into the existing APC structure.

We note that we will also publish on the CMS Web site at *http://www.cms.hhs.gov/HospitalOutpatientPPS/01_overview.asp* a list of all procedural APCs with the CY 2009 portions of the APC payment amounts that we determine are associated with the cost of devices. These portions will be used as the APC offset amounts, and, in accordance with our established practice, they will 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, as specified in our regulations at § 419.66(d).

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

1. Background

In recent years, there have been several field actions on and recalls of medical devices as a result of implantable device failures. In many of these cases, the manufacturers have offered devices without cost to the hospital or with credit for the device being replaced if the patient required a more expensive device. In order to ensure that payment rates for procedures involving devices reflect only the full costs of those devices, our standard ratesetting methodology for device-dependent APCs uses only claims that contain the correct device code for the procedure, do not contain token charges, and do contain the ''FB'' modifier signifying that the device was furnished without cost or with a full credit.

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 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 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. In CY 2008, OPPS payment for the implantation procedure is reduced 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 ''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 policy (72 FR 66743 through 66749).

2. APCs and Devices Subject to the Adjustment Policy

In the CY 2009 OPPS/ASC proposed rule (73 FR 41478 through 41480), for CY 2009 we proposed to continue the 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 that 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 final rule with comment period for a description of our standard ratesetting methodology for device-dependent APCs.) Moreover, the payment for these devices comprises a large part of the APC payment on which the beneficiary copayment is based, and we continue to believe it is equitable that the beneficiary cost sharing reflect the reduced costs in these cases.

We also proposed to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which this policy applies (71 FR 68072 through 68077). Specifically, (1) all procedures assigned to the selected APCs must involve implantable devices that would be reported if device insertion procedures were performed, (2) the required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedures (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 proposed to continue to restrict the devices to which the APC payment adjustment would apply to a specific set of costly devices to ensure that the adjustment would not be triggered by the implantation of an inexpensive device whose cost would not constitute a significant proportion of the total payment rate for an APC. We continue to believe that these criteria are appropriate because free devices and credits are likely to be associated with particular cases only when the device must be reported on the claim and is of a type that is implanted and remains in the body when the beneficiary leaves the hospital. We believe that the reduction in payment is appropriate only when the cost of the device is a significant part of the total cost of the APC into which the device cost is packaged, and that the 40-percent threshold is a reasonable definition of a significant cost.

As indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41479), we examined the offset amounts calculated from the CY 2009 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 2008 continue to meet the criteria for CY 2009, and to determine whether other APCs to which the policy does not apply in CY 2008 would meet the criteria for CY 2009. Table 18 of the CY 2009 OPPS/ASC proposed rule listed the proposed APCs to which the payment reduction policy for no cost/full credit and partial credit devices would apply in CY 2009 and displayed the proposed payment reduction percentages for both no cost/full credit and partial credit circumstances. Table 19 of the CY 2009 OPPS/ASC proposed rule listed the proposed devices to which this policy would apply in CY 2009. As reflected in the tables, we proposed to add APC 0425 (Level II Arthroplasty or Implantation with Prosthesis) and APC 0648 (Level IV Breast Surgery) and their associated devices that would not otherwise be on the device list for CY 2009 because the device offset percentages for these two APCs were above the 40-percent threshold based on the CY 2007 claims data available for the proposed rule. We also proposed to remove APC 0106 (Insertion/Replacement of Pacemaker Leads and/or Electrodes) and device HCPCS codes associated only with procedures assigned to this APC because the proposed device offset percentage for this APC was less than 40 percent. We stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41479) that we would update the lists of APCs and devices to which the no cost/full credit and partial credit device adjustment policy would apply in CY 2009 based on the final CY 2007 claims data available for this final rule with comment period.

Comment: One commenter supported the continuation of the current policy. Another commenter acknowledged an understanding of the rationale for the no cost/full credit and partial credit payment reduction policy, but expressed concerns regarding the policy's application in cases of device upgrades. According to the commenter, when a device is replaced, the old model is often no longer available and an upgrade is required. In such circumstances, the commenter asserted that the full cost of the replaced device is credited, but the replacement device is more expensive. The commenter objected to CMS' application of the full device offset amount in these cases, and suggested CMS develop a process that takes into account and pays for the excess cost of the replacement device. The commenter also noted that, in instances of partial credits for replacement devices, hospitals often do not know if they are receiving a partial credit until the manufacturer has inspected the device. According to the commenter, hospitals must then resubmit the claim after the partial refund is received. The commenter believed that this process requires manual intervention that is costly for hospitals because many material management systems are interfaced with billing systems and do not routinely match returns to specific patients. The commenter urged CMS to take into account the additional costs incurred by the hospital to track these replacement devices and the additional staff effort required to resubmit claims when the manufacturer provides partial credit for replacement devices.

Response: We do not agree with the commenter that we need to modify the no cost/full credit and partial credit device adjustment policy to account for the cost of more expensive replacement devices when manufacturers provide device upgrades. We continue to believe making the full APC payment would result in significant overpayment because, as described above, we use only those claims that reflect the full costs of devices in ratesetting for device-dependent APCs. In cases where a hospital incurs a cost for a device upgrade, the difference between the cost of the replacement device and the full credit the hospital receives for the device being replaced would likely be much less than the full cost of the device that is included in the device-dependent APC payment rate. To provide the full APC payment in these cases would favor a device upgrade, rather than replacement with a comparable device, in warranty or recall cases where the surgical procedure to replace the device is only medically necessary because of the original defective device, for which the manufacturer bears responsibility. Moreover, we also are concerned that a new policy to apply a smaller APC payment percentage reduction in an upgrade case, if we were eventually able to estimate such a percentage from sufficient claims data, could also favor device upgrades, rather than replacement with a comparable device in those situations for which the upgrade is only being provided because the old model failed (and for which the manufacturer provides a full credit) but is no longer available for use in the replacement procedure. We recognize that, in some cases, the estimated device cost, and, therefore, the amount of the payment reduction, will be more or less than the cost a hospital would otherwise incur for a no cost/full credit device. However, because averaging is inherent in a prospective payment system, we do not believe this is inappropriate. Therefore, we continue to believe that the full device offset reduction should be made when hospitals receive full credit for the cost of a replaced device

against the cost of a more expensive replacement device.

Also, as stated in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68076), we do not believe it is necessary to reduce the amount of no cost/full credit and partial credit device adjustments to account for administrative costs because we believe that these costs are part of the payment that remains for the services furnished. We remind hospitals that, as outlined in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66747), they have two options to report that they received a partial credit of 50 percent or more of the cost of a replacement device: (1) Submit the claims immediately without the ''FC'' modifier signifying partial credit for a replacement device and submit a claim adjustment with the ''FC'' modifier at a later date once the credit determination is made; or (2) hold the claim until a determination is made on the level of credit.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to continue the established no cost/full credit and partial credit device adjustment policy. For CY 2009, OPPS payments for implantation procedures to which the ''FB'' modifier is appended are reduced by 100 percent of the device offset for no cost/full credit cases when both a device code listed in Table 22, below, is present on the claim and the procedure code maps to an APC listed in Table 21 below. OPPS payments for implantation procedures to which the ''FC'' modifier is appended are reduced by 50 percent of the device offset when both a device code listed in Table 22 is present on the claim and the procedure code maps to an APC listed in Table 21. Beneficiary copayment is based on the reduced payment amount when either the ''FB'' or ''FC'' modifier is billed and the procedure and device codes appear on the lists of procedures and devices to which this policy applies.

In addition, we are adding, as proposed, APC 0425 (Level II Arthroplasty or Implantation with Prosthesis) and APC 0648 (Level IV Breast Surgery) and their associated devices to the lists of APCs and devices to which this policy applies, as shown in Tables 21 and 22, respectively, because the device offset percentages for these two APCs are above the 40-percent threshold. We are not implementing our proposal to remove APC 0106 (Insertion/Replacement of Pacemaker Leads and/or Electrodes) and device HCPCS codes associated with this APC from these lists because the device offset percentage for this APC is now above 40 percent based on updated CY 2007 claims data and the most recent cost report data available for this final rule with comment period.

TABLE 21—APCS TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY APPLIES

Final CY 2009 APC	Final CY 2009 SI	CY 2009 APC title	Final CY 2009 device offset percentage for no cost/full credit case	Final CY 2009 device offset percentage for partial credit case
0039	S	Level I Implantation of Neurostimulator	84	42
0040	S	Percutaneous Implantation of Neurostimulator Electrodes	57	29
0061	S	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electrodes.	62	31
0089	T	Insertion/Replacement of Permanent Pacemaker and Electrodes.	72	36
0090	T	Insertion/Replacement of Pacemaker Pulse Generator	74	37
0106	T	Insertion/Replacement of Pacemaker Leads and/or Electrodes.	43	21
0107	T	Insertion of Cardioverter-Defibrillator	89	45
0108	T	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads.	89	44
0222	S	Level II Implantation of Neurostimulator	85	42
0225	S	Implantation of Neurostimulator Electrodes, Cranial Nerve.	62	31
0227	T	Implantation of Drug Infusion Device	82	41
0259	T	Level VII ENT Procedures	84	42
0315	S	Level III Implantation of Neurostimulator	88	44
0385	S	Level I Prosthetic Urological Procedures	59	29
0386	S	Level II Prosthetic Urological Procedures	69	34
0418	T	Insertion of Left Ventricular Pacing Elect	71	36
0425	T	Level II Arthroplasty or Implantation with Prosthesis	59	29
0648	T	Level IV Breast Surgery	46	23
0654	T	Insertion/Replacement of a permanent dual chamber pacemaker.	77	38
0655	T	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker.	76	38
0680	S	Insertion of Patient Activated Event Recorders	71	36
0681	T	Knee Arthroplasty	71	35

TABLE 22—DEVICES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY APPLIES

CY 2009 device HCPCS code	CY 2009 short descriptor
C1721	AICD, dual chamber.
C1722	AICD, single chamber.
C1728	Cath, brachytx seed adm.
C1764	Event recorder, cardiac.
C1767	Generator, neurostim, imp.

TABLE 22—DEVICES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY APPLIES—Continued

CY 2009 device HCPCS code	CY 2009 short descriptor
C1771	Rep dev, urinary, w/sling.
C1772	Infusion pump, programmable.
C1776	Joint device (implantable).
C1777	Lead, AICD, endo single coil.
C1778	Lead, neurostimulator.
C1779	Lead, pmkr, transvenous VDD.
C1785	Pmkr, dual, rate-resp.
C1786	Pmkr, single, rate-resp.
C1789	Prosthesis, breast, imp.
C1813	Prosthesis, penile, inflatab.
C1815	Pros, urinary sph, imp.
C1820	Generator, neuro rechg bat sys.
C1881	Dialysis access system.
C1882	AICD, other than sing/dual.
C1891	Infusion pump, non-prog, perm.
C1895	Lead, AICD, endo dual coil.
C1896	Lead, AICD, non sing/dual.
C1897	Lead, neurostim, test kit.
C1898	Lead, pmkr, other than trans.
C1899	Lead, pmkr/AICD combination.
C1900	Lead coronary venous.
C2619	Pmkr, dual, non rate-resp.
C2620	Pmkr, single, non rate-resp.
C2621	Pmkr, other than sing/dual.
C2622	Prosthesis, penile, non-inf.
C2626	Infusion pump, non-prog, temp.
C2631	Rep dev, urinary, w/o sling.
L8600	Implant breast silicone/eq.
L8614	Cochlear device/system.
L8685	Implt nrostm pls gen sng rec.
L8686	Implt nrostm pls gen sng non.
L8687	Implt nrostm pls gen dua rec.
L8688	Implt nrostm pls gen dua non.
L8690	Aud osseo dev, int/ext comp.

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

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

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biological agents. As originally 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 (before enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 (Pub. L. 106–554), on December 21, 2000).

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 can be made for at least 2 years but not more than 3 years. CY 2009 pass-through drugs and biologicals and their APCs are assigned status indicator ''G'' as indicated in Addenda A and B to this final rule with comment period.

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 (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 to be 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) 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. 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, as added by section 303(c) of Public Law 108–173, 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 final rule with comment period, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on the CMS Web site at: *http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01_overview.asp#TopOfPage*.

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, as added by section 303(d) of Public Law 108–173, 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 includes approximately 190 of the most common Part B drugs provided in the physician's office setting. We note that the Part B drug CAP program has been postponed for CY 2009 (Medicare Learning Network (MLN) Matters Special Edition 0833, available via the Web site: *http://www.medicare.gov*). Therefore, there will be no effective Part B drug CAP rate for pass-through drugs and biologicals as of January 1, 2009. As is our standard process, we have used the Part B drug CAP rates for July 2008 to determine the packaging status for drugs with expiring pass-through status. However, effective January 1, 2009, we will use the amount determined under section 1842(o) of the Act for payment purposes for drugs and biologicals with pass-through status. If the Part B drug CAP program is reinstituted sometime during CY 2009, we will 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 will continue to use the rate that would be paid in the physician's office setting for drugs and biologicals with pass-through status. The list of drugs and biologicals covered under the Part B drug CAP through December 31, 2008, their associated payment rates, and the Part B drug CAP pricing methodology can be found on the CMS Web site at: *http://www.cms.hhs.gov/CompetitiveAcquisforBios*.

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 CY 2008, we estimated the OPPS pass-through payment amount for drugs and biologicals to be $6.6 million. Our OPPS pass-through payment estimate for drugs and biologicals in CY 2009 is $23.3 million, which is discussed in section VI.B. of this final rule with comment period.

The pass-through application and review process for drugs and biologicals is explained on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp*.

2. Drugs and Biologicals With Expiring Pass-Through Status in CY 2008

Section 1833(t)(6)(C)(i) of the Act specifies that the duration of transitional pass-through payments for drugs and biologicals must be no less than 2 years and no longer than 3 years. In the CY 2009 OPPS/ASC proposed rule (73 FR 41481), we proposed that the pass-through status of 15 drugs and biologicals would expire on December 31, 2008, as listed in Table 20 of the proposed rule. It is standard OPPS practice to delete temporary C-codes if an alternate permanent HCPCS code becomes available for purposes of OPPS billing and payment. Based on our review of the new CY 2009 HCPCS codes available at the time of this final rule with comment period, as noted in Table 23 below, there are no new permanent HCPCS codes that will be implemented in CY 2009 to replace HCPCS C-codes that were used in CY 2008 for drugs and biologicals with pass-through status.

In addition, HCPCS code J7348 (Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, without metabolically active elements (Tissuemend), per square centimeter), which was proposed for expiring pass-through status on December 31, 2009, has been deleted by the CMS HCPCS Workgroup, effective January 1, 2009. We have determined that the product(s) described by this HCPCS code are appropriately reported with HCPCS code Q4109 (Skin substitute, Tissuemend, per square centimeter), effective January 1, 2009. Furthermore, another HCPCS code J7349 (Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, without metabolically active elements (Primatrix), per square centimeter), which was proposed for expiring pass-through status on December 31, 2008, also has been deleted, effective January 1, 2009, and product(s) described by this HCPCS code are appropriately reported with HCPCS code Q4110 (Skin substitute, Primatrix, per square centimeter).

As we discussed in the proposed rule, 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 was proposed at $60 for CY 2009). If the estimated per day cost is less than or equal to the applicable OPPS drug packaging threshold, we 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 is greater than the OPPS drug packaging threshold, we provide separate payment at the applicable relative ASP-based payment amount (which was proposed at ASP+4 percent for CY 2009). For drugs and biologicals that are currently covered under the CAP, we proposed to use the payment rates calculated under that program that were in effect as of April 1, 2008, for purposes of packaging decisions and for Addenda A and B to the proposed rule. As we proposed, we are updating these payment rates based on the CAP rates as of July 1, 2008, for packaging decisions and as of October 1, 2008, for purposes of Addenda A and B to this CY 2009 OPPS/ASC final rule with comment period, as these are the most updated data available at the time these decisions are made.

Three of the products with proposed expiring pass-through status for CY 2009 are biologicals that are solely surgically implanted according to their Food and Drug Administration-approved indications. As discussed in the proposed rule, these products are described by HCPCS codes C9352 (Microporous collagen implantable tube (Neuragen Nerve Guide), per centimeter length); C9353 (Microporous collagen implantable slit tube (NeuraWrap Nerve Protector), per centimeter length); and J7348 (Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, without metabolically active elements (Tissuemend), per square centimeter). We note that, as discussed above, the CMS HCPCS Workgroup has deleted HCPCS code J7348, effective January 1,

2009, and we have determined that the product(s) described by this HCPCS code are appropriately reported with HCPCS code Q4109, effective January 1, 2009.

We proposed to package payment for those implantable biologicals that have expiring pass-through status in CY 2009 into payment for the associated surgical procedure. We indicated our belief that the three products described above with expiring pass-through status for CY 2009 differ from other biologicals paid under the OPPS in that they specifically function as surgically implanted devices. Both implantable devices under the OPPS and these three biologicals with expiring pass-through status are always surgically inserted or implanted (including through a surgical incision or a natural orifice). Furthermore, in some cases, these implantable biologicals can substitute for implantable nonbiologic devices (such as for synthetic nerve conduits or synthetic mesh used in tendon repair).

To date, for other nonpass-through biologicals paid under the OPPS that may sometimes be used as implantable devices, we have instructed hospitals, via Transmittal 1336, Change Request 5718, dated September 14, 2007, to not separately bill for the HCPCS codes for the products when using these items as implantable devices (including as a scaffold or an alternative to human or nonhuman connective tissue or mesh used in a graft) during surgical procedures. In such cases, we consider payment for the biological used as an implantable device in a specific clinical case to be included in payment for the surgical procedure.

As we established in the CY 2003 OPPS final rule with comment period (67 FR 66763), when the pass-through payment period for an implantable device ends, it is standard OPPS policy to package payment for the implantable device into payment for its associated surgical procedure. We consider nonpass-through implantable devices to be integral and supportive items and services for which packaged payment is most appropriate. 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. Therefore, when the period of nonbiologic device pass-through payment ends, we package the costs of the devices no longer eligible for pass-through payment into the costs of the procedures with which the devices were reported in the claims data used to set the payment rates for the upcoming calendar year. As described in the CY 2009 OPPS/ASC proposed rule (73 FR 41481), we believed that this policy to package payment for implantable devices that are integral to the performance of separately paid procedures should also apply to payment for implantable biologicals without pass-through status, when those biologicals function as implantable devices. As stated above, implantable biologicals may be used in place of other implantable nonbiologic devices whose costs are already accounted for in the associated procedural APC payments for surgical procedures. If we were to provide separate payment for these implantable biologicals without pass-through status, we would potentially be providing duplicate device payment, both through the packaged nonbiologic device cost included in the surgical procedure's payment and separate biological payment. We indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41481) that we saw no basis for treating implantable biological and nonbiologic 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.

The methodology of calculating a product's estimated per day cost and comparing it to the annual OPPS drug packaging threshold has been used to determine the packaging status of all drugs and biologicals under the OPPS (except for our exemption for 5HT3 anti-emetics), including injectable products paid for under the OPPS as biologicals (such as intraarticular sodium hyaluronate products). However, because we believe that the three products described above with expiring pass-through status for CY 2009 differ from other biologicals paid under the OPPS in that they specifically function as surgically implanted devices, we proposed a policy to package payment for any biological without pass-through status that is surgically inserted or implanted (through a surgical incision or a natural orifice) into the payment for the associated surgical procedure when their pass-through status expires.

Comment: One commenter requested that CMS not end pass-through status for HCPCS codes C9352 and C9353 effective December 31, 2008. The commenter pointed out that while these two products were originally granted pass-through status on January 1, 2007 (and could therefore theoretically be eligible for another year of pass-through status under the OPPS), a coding change in CY 2008 was the first opportunity for these products to be differentiated on hospital claims. Therefore, when determining payment rates for CY 2009, the commenter argued that CY 2007 claims data do not identify which product was used on the claim and, therefore, accurate payment cannot be determined for these products for CY 2009.

In addition, the commenter stated that there were very few claims for these products in CY 2007. There were a total of 11 CY 2007 claims for these products, and only 3 were single or ''pseudo'' single claims used for ratesetting for the associated procedures.

Response: HCPCS code C9350 (Microporous collagen tube of non-human origin, per centimeter length) was first created effective January 1, 2007 and was assigned status indicator ''G'' (indicating pass-through status applied). On January 1, 2008, HCPCS code C9350 was split into HCPCS code C9352 and HCPCS code C9353. The products described in CY 2007 under HCPCS code C9350 continued pass-through status under the HCPCS codes C9352 and C9353 in CY 2008. As stated above, pass-through status is required for at least 2 but not more than 3 years. We proposed to end pass-through status for the products described by HCPCS codes C9352 and C9353 because they were first approved for pass-through status on January 1, 2007 under HCPCS code C9350 and, therefore, would meet the timeframe required for pass-through status on December 31, 2008. We do not believe the finding that these products were rarely used in the care of Medicare beneficiaries in CY 2007, their first year of pass-through payment, is sufficient justification for providing a third year of pass-through payment, as we have cost data that allow us to package payment for these implantable biologicals into payment for the associated procedures for CY 2009.

We note that, unlike our standard methodology of calculating an estimated per day cost for items that have expiring pass-through status and comparing this estimate to the applicable drug packaging threshold, our proposal to package nonpass-through biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the payment for the associated surgical procedure is not dependent on claims data to establish an estimated per day cost for each product. Rather, the packaging determination is made as a result of the

FDA-indicated implantable use of the product. Therefore, we do not believe that the coding change in CY 2008 and the resulting lack of product-specific claims data sufficiently warrant an extension of pass-through status for the products described by HCPCS codes C9352 and C9353.

Comment: A few commenters supported the proposed methodology to package payment for drugs and nonimplantable biologicals with expiring pass-through status if their estimated per day costs are less than or equal to the drug packaging threshold (proposed at $60 for CY 2009).

Furthermore, several commenters supported CMS' proposal to package payment for implantable biologicals without pass-through status into the payment for the associated surgical procedure. One commenter recommended that CMS continue to examine the APC weights of these associated APCs to ensure they sufficiently account for the costs of the implantable biologicals. In addition, this commenter recommended that CMS consider developing separate APCs for surgical procedures that use biological and synthetic mesh from those procedures that do not use any type of mesh. The commenter argued that this separation would ensure that the APCs are similar in terms of clinical characteristic and resource use.

One commenter requested an exception to the proposed packaging policy when the procedure including an implantable biological is billed using an unlisted surgical procedure code. In this specific situation, the commenter believed that the implantable biological should be paid separately whether or not it currently has pass-through status if the estimated per day cost is over the applicable drug packaging threshold.

Response: We proposed to package payment for drugs and nonimplantable biologicals with expiring pass-through status in CY 2009 and with estimated costs below the CY 2009 $60 drug packaging threshold and to continue to pay separately for these products if their estimated costs exceeded the threshold, consistent with our established policy for the past several years. We appreciate the commenters' support for this approach.

In addition, we do not believe there is a need to develop separate APCs for surgical procedures that use biological and synthetic mesh, distinct from APCs for those procedures that do not use mesh. The APCs are groupings of services that share clinical and resource characteristics. The packaged costs of implantable mesh devices are reflected in the HCPCS code-specific median costs for the associated surgical procedures; thus, while we believe that, unless we find that APCs violate the 2 times rule or there is a concern regarding their clinical or resource homogeneity, we have no specific need to assign procedures using mesh to different APCs from procedures that do not implant mesh products. 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 supportive items and services into the payment for the independent procedure or service with which they are associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility.

Finally, we understand that one commenter was concerned that when implantable biologicals are used in procedures reported with unlisted surgical procedure CPT codes, the complete packaged payment for the procedure and the biological may not sufficiently cover the costs of the biological. We disagree with the commenter that implantable biologicals should be paid separately when provided with an unlisted surgical procedure. We acknowledge that the commenter's concern is based partially on our established policy to provide payment for unlisted codes at the lowest level clinical APC in an appropriate clinical series. As we do for other OPPS services, we package payment for certain items and services when provided with unlisted procedure codes. We note that this methodology is also followed when packaged implantable nonbiologic devices are provided with unlisted surgical procedure codes. We expect that stakeholders would continue to seek specific HCPCS codes for new procedures provided with any frequency in the HOPD in order to allow for more precise procedure-specific payment under the OPPS. We remind readers that the reporting of unlisted codes is meant as a temporary measure to allow payment for new and/or uncommon services and, therefore, the services described by unlisted codes vary from year-to-year.

Comment: One commenter further recommended that CMS treat biologicals that are always surgically implanted or inserted and are approved by the FDA as devices rather than drugs for purposes of pass-through payment. The commenter noted that this would allow all implantable devices, biological and otherwise, to be subject to a single pass-through payment policy. The commenter concluded that this policy change would provide consistency in billing these products as implanted devices during both their pass-through payment period, as well as after the expiration of pass-through status.

Response: We appreciate the commenter's recommendation to treat biologicals that are always surgically implanted or inserted and are approved by the FDA as devices for purposes of pass-through payment under the OPPS. We did not propose such a policy for CY 2009, but we will consider making such a proposal for future rulemaking.

Comment: One commenter requested special payment consideration for HCPCS code J1473 (Injection, idursulfase, 1mg) because this drug has been granted orphan drug status by the FDA. Specifically, the commenter requested separate payment for this drug.

Response: In the CY 2009 OPPS/ASC proposed rule, we proposed to end the pass-through status of HCPCS code J1473 on December 31, 2008. As noted above, for drugs and biologicals (other than implantable only biologicals) transitioning from pass-through status, we determine the packaging status of each drug or biological by comparing its estimated per day cost to the annual drug packaging threshold for the applicable payment year. For CY 2009, the per day cost estimate for HCPCS code J1473 exceeds the $60 drug packaging threshold finalized for CY 2009 in section V.B.2.b. of this final rule with comment period and, therefore, HCPCS code J1473 will be paid separately for CY 2009.

After consideration of the public comments received, for CY 2009, we are finalizing our proposed policy, without modification, to package payment for any biological without pass-through status that is surgically inserted or implanted (through a surgical incision or a natural orifice) into the payment for the associated surgical procedure. As a result of this final methodology, HCPCS codes C9352, C9353, and J7348 are packaged and assigned status indicator ''N'' in Addendum B to this final rule with comment period. In addition, as proposed, any new biologicals without pass-through status that are surgically inserted or implanted (through a surgical incision or a natural orifice) will be packaged beginning in CY 2009.

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 when the products are used as implantable devices.

For drugs and nonimplantable biologicals with expiring pass-through status, as proposed we have determined their final CY 2009 payment methodology of packaged or separate payment based on their estimated per day costs, in comparison with the CY 2009 drug packaging threshold.

Finally, we are finalizing our CY 2009 proposal, without modification, to expire pass-through status for the 15 drugs and biologicals listed in Table 20 of the proposed rule and listed below in Table 23, effective December 31, 2008. Packaged drugs and biologicals are assigned status indicator ''N'' and drugs and biologicals that continue to be separately paid as nonpass-through products are assigned status indicator ''K.''

TABLE 23—DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS EXPIRES DECEMBER 31, 2008

CY 2008 HCPCS code	CY 2009 HCPCS code	CY 2009 short descriptor	Final CY 2009 SI	Final CY 2009 APC
C9352	C9352	Neuragen nerve guide, per cm	N	
C9353	C9353	Neurawrap nerve protector, cm	N	
J0129*	J0129	Abatacept injection	K	9230
J0348	J0348	Injection, anidulafungin, 1mg	K	0760
J0894*	J0894	Decitabine injection	K	9231
J1740*	J1740	Ibandronate sodium injection	K	9229
J1743	J1743	Idursulfase injection	K	9232
J2248	J2248	Micafungin sodium injection	K	9227
J2323*	J2323	Natalizumab injection	K	9126
J2778*	J2778	Ranibizumab injection	K	9233
J3243	J3243	Tigecycline injection	K	9228
J3473	J3473	Hyaluronidase recombinant	K	0806
J7348	Q4109	Tissuemend skin sub	N	
J7349	Q4110	Primatrix skin sub	K	1248
J9303	J9303	Panitumumab injection	K	9235

*Indicates that the drug was paid at a rate determined by the Part B drug CAP methodology (prior to January 1, 2009) while identified as pass-through under the OPPS.

3. Drugs, Biologicals, and Radiopharmaceuticals With New or Continuing Pass-Through Status in CY 2009

In the CY 2009 OPPS/ASC proposed rule (73 FR 41482), we proposed to continue pass-through status in CY 2009 for 16 drugs and biologicals. These items, which were approved for pass-through status between April 1, 2007 and July 1, 2008, were listed in Table 21 of the proposed rule. The APCs and HCPCS codes for the proposed drugs and biologicals that were listed in Table 21 were assigned status indicator ''G'' in Addenda A and B to the 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 year established under such section as calculated and adjusted by the Secretary) and the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. We stated in the proposed rule that, given our CY 2009 proposal to provide payment for nonpass-through separately payable drugs and biologicals at ASP+4 percent as described further in section V.B.3. of the proposed rule, we believed it would be consistent with the statute to provide payment for drugs and biologicals with pass-through status that are not part of the Part B drug CAP at a rate of ASP+6 percent, the amount authorized under section 1842(o) of the Act, rather than ASP+4 percent that would be the otherwise applicable fee schedule portion associated with the drug or biological. The difference between ASP+4 percent and ASP+6 percent, therefore, would be the CY 2009 pass-through payment amount for these drugs and biologicals. Thus, for CY 2009, we proposed to pay for pass-through drugs and biologicals that are not part of the Part B drug CAP at ASP+6 percent, equivalent to the rate these drugs and biologicals would receive in the physician's office setting in CY 2009. In addition, as we consider radiopharmaceuticals to be drugs for pass-through purposes, we proposed to provide pass-through payment for radiopharmaceuticals based on the ASP methodology at a rate equivalent to the payment rate for drugs and biologicals in the physician's office setting. We proposed to collect ASP data from those manufacturers that were able to report a patient-specific dose based on the HCPCS code descriptor (73 FR 41482).

Section 1842(o) of the Act also states that if a drug or biological is covered under the CAP 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 year established as calculated and adjusted by the Secretary. For CY 2009, we proposed to provide payment for drugs and biologicals with pass-through status that are offered under the Part B drug CAP at a rate equal to the Part B drug CAP rate. Therefore, considering ASP+4 percent to be the otherwise applicable fee schedule portion associated with these drugs or biologicals, the difference between the Part B drug CAP rate and ASP+4 percent would be the pass-through payment amount for these drugs and biologicals. In the proposed rule, HCPCS codes that are offered under the CAP program as of April 1, 2008, were identified in Table 21 of the proposed rule with an asterisk.

Comment: Several commenters supported the continued pass-through status in CY 2009 of specific drugs and biologicals and urged CMS to finalize the proposal for these items. One commenter supported the proposed methodology of providing payment for drugs and biologicals at a rate equal to the rate those drugs and biologicals would receive under the Part B drug CAP program or in the physician's office setting. The commenter stated that

newer drugs with pass-through status are often not part of discounting programs for either physicians or hospitals, and that payment parity for this group of drugs provides for continued access to these new therapies. Another commenter disagreed with the proposed payment methodology for drugs, biologicals, and radiopharmaceuticals that have pass-through status. The commenter noted that linking pass-through drug payment to the payment provided to physicians creates a further payment disadvantage for hospitals, as the commenter believed that physicians may charge for consulting services that assist in paying for physicians' costs of supplying drugs, while hospitals do not have this same opportunity.

Response: As discussed above, we are directed by section 1833(t)(6)(D) of the Act to provide payment for pass-through drugs and biologicals at the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological (or at the Part B Drug CAP rate if the drug or biological is covered under the Part B drug CAP). Therefore, we are not able to adopt an alternative payment methodology for pass-through drugs and biologicals under the CY 2009 OPPS.

Comment: A few commenters requested clarification of the criteria that would be used to evaluate radiopharmaceutical and contrast agent applications for pass-through status. In addition, some commenters requested that CMS clarify that new contrast agents are eligible to apply for pass-through status, even though they would otherwise be packaged.

Response: We note that, as stated above, for pass-through purposes we consider radiopharmaceuticals and contrast agents to be drugs and, therefore, the same pass-through criteria apply. Our criteria for reviewing pass-through drug and biologicals applications are available on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp*.

Under the packaging methodology for diagnostic radiopharmaceuticals and contrast agents that we implemented in CY 2008, new diagnostic radiopharmaceuticals and new contrast agents without pass-thorough status would be packaged under the OPPS. As we are continuing our packaging policy for diagnostic radiopharmaceuticals and contrast agents for CY 2009, we will continue to package payment for all new diagnostic radiopharmaceuticals and contrast agents that do not have pass-through status in CY 2009.

Comment: Several commenters supported the proposal to provide payment for pass-through diagnostic and therapeutic radiopharmaceuticals based on the ASP methodology. Other commenters, while generally in favor of using the ASP methodology for pass-through radiopharmaceutical payment purposes, cautioned CMS that some manufacturers do not have the ability to provide a patient-specific ASP for their product(s).

Response: We appreciate the commenters' support for the ASP methodology to pay for radiopharmaceuticals with pass-through status. Currently, there are no radiopharmaceuticals (diagnostic or therapeutic) that would have pass-through status in CY 2009. For CY 2009, we proposed to provide payment for diagnostic and therapeutic radiopharmaceuticals with pass-through status based on the ASP methodology. We proposed to collect ASP data from those manufacturers who were able to report a patient-specific dose based on the HCPCS code descriptor (73 FR 41482).

Shortly after the issuance of our CY 2009 proposed rule, section 142 of Public Law 110–275 (MIPPA) directed that OPPS payments for therapeutic radiopharmaceutical be made at hospital charges adjusted to cost for CY 2009. The payment methodology specified in Public Law 110–275 also applies to any therapeutic radiopharmaceutical with pass-through status during CY 2009. Therefore, any therapeutic radiopharmaceutical that is granted pass-through status for CY 2009 will be paid based on hospital charges adjusted to cost for CY 2009.

Consistent with OPPS payment for separately payable drugs and biologicals with HCPCS codes, in CY 2009, as proposed, payment for diagnostic radiopharmaceuticals that are granted pass-through status will be based on the ASP methodology. As stated above, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic radiopharmaceutical receives pass-through status during CY 2009, we will follow the standard ASP methodology to determine its pass-through payment rate under the OPPS.

We understand that not all manufacturers are in a position to submit patient-specific ASP data for their diagnostic radiopharmaceuticals. Therefore, if we do not have ASP data submitted under the standard ASP process to provide payment at ASP+6 percent, we will base the pass-through payment on the product's wholesale acquisition cost (WAC). If WAC data are also not available, we will provide payment for the pass-through diagnostic radiopharmaceutical at 95 percent of its most recent average wholesale price (AWP).

Comment: Some commenters suggested that CMS provide a payment, in addition to the relative ASP amount, for pass-through radiopharmaceuticals to account for nuclear medicine handling and compounding costs.

Response: As stated above, we are directed by section 142 of Public Law 110–275 to provide payment for therapeutic radiopharmaceuticals with pass-through status in CY 2009 at charges adjusted to cost. Therefore, additional payments are not within our discretion for these therapeutic radiopharmaceuticals. However, as we stated in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68096), we believe that hospitals have the ability to set charges for items properly so that charges adjusted to cost can appropriately account fully for the acquisition and overhead costs of radiopharmaceuticals.

We have routinely provided a single payment for drugs, biologicals, and radiopharmaceuticals under the OPPS to account for acquisition cost and pharmacy overhead costs, including compounding costs. We continue to believe that a single payment is appropriate for diagnostic radiopharmaceuticals with pass-through status in CY 2009, and that the payment rate of ASP+6 (or payment based on the ASP methodology) is adequate to provide payment for both the diagnostic radiopharmaceutical acquisition cost and any associated nuclear medicine handling and compounding costs.

Comment: Some commenters noted that a pass-through period of possibly only 2 years discourages new product development, especially for radiopharmaceutical products. One commenter recommended providing pass-through payment for approved radiopharmaceuticals for a full 3-year time period to allow hospitals time to incorporate new products into their chargemasters and billing practices.

Response: As stated above, we currently do not have any radiopharmaceuticals, diagnostic or therapeutic, that either have been granted pass-through status or are under consideration for pass-through status at the time of this final rule with comment period. We also note that the OPPS pass-through provision provides for at least 2 but not more than 3 years of pass-through payment for drugs and biologicals that are approved for pass-

through payments. We provide an annual opportunity through the annual OPPS/ASC rulemaking cycle for public comment on those drugs and biologicals that are proposed for expiration of pass-through payment in the next calendar year. We often receive comments related to our proposed expiration of pass-through status for particular items, and we expect to continue to receive these comments regarding the proposed expiration of pass-through status for drugs and biologicals in the future. In this manner, we would address specific concerns about the pass-through period for individual drugs and biologicals in the future, including radiopharmaceuticals.

After consideration of the public comments received, we are finalizing our proposed CY 2009 policy, with modification as noted below, to provide payment for pass-through drugs, including diagnostic radiopharmaceuticals, and biologicals based on the ASP methodology. This allows diagnostic radiopharmaceutical manufacturers that are able to provide ASP information through the established methodology to be paid for pass-through diagnostic radiopharmaceuticals at ASP+6 percent, the same rate as pass-through drugs and biologicals are paid in the physician's office setting. In addition, we are modifying our proposal to provide payment for therapeutic radiopharmaceuticals with pass-through status based on the requirements of section 142 of Public Law 110–275. Therefore, therapeutic radiopharmaceuticals with pass-through status in CY 2009 will be paid at hospital charges adjusted to cost, the same payment methodology as other therapeutic radiopharmaceuticals in CY 2009.

The drugs and biologicals that are continuing pass-through status or have been granted pass-through status as of January 2009 for CY 2009 are displayed in Table 24 below. In addition, we did not receive any public comments on our proposal to update pass-through payment rates on a quarterly basis on our Web site during CY 2009 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through drugs and biologicals are necessary, and we are finalizing this policy. Finally, if a drug or biological that has been granted pass-through status for CY 2009 becomes covered under the Part B drug CAP if the program is reinstituted, we will provide payment for Part B drugs that are granted pass-through status and are covered under the Part B drug CAP at the Part B drug CAP rate. Appropriate adjustments to the payment rates for pass-through drugs and biologicals will occur on a quarterly basis.

TABLE 24—DRUGS AND BIOLOGICALS WITH PASS-THROUGH STATUS IN CY 2009

CY 2008 HCPCS code	CY 2009 HCPCS code	CY 2009 short descriptor	Final CY 2009 SI	Final CY 2009 APC
C9238	J1953	Levetiracetam injection	G	9238
C9239	J9330	Temsirolimus injection	G	1168
C9240*	J9207	Ixabepilone injection	G	9240
C9241	J1267	Doripenem injection	G	9241
C9242	J1453	Fosaprepitant injection	G	9242
C9243	J9033	Bendamustine injection	G	9243
C9244	J2785	Injection, regadenoson	G	9244
C9354	C9354	Veritas collagen matrix, cm2	G	9354
C9355	C9355	Neuromatrix nerve cuff, cm	G	9355
C9356	C9356	TendoGlide Tendon Prot, cm2	G	9356
C9357	Q4114	Integra flowable wound matri	G	1251
C9358	C9358	SurgiMend, 0.5cm2	G	9358
C9359	C9359	Implant, bone void filler	G	9359
J1300	J1300	Eculizumab injection	G	9236
J1571	J1571	Hepagam b im injection	G	0946
J1573	J1573	Hepagam b intravenous, inj	G	1138
J3488*	J3488	Reclast injection	G	0951
J9225*	J9225	Vantas implant	G	1711
J9226	J9226	Supprelin LA implant	G	1142
J9261	J9261	Nelarabine injection	G	0825
Q4097	J1459	Inj IVIG privigen 500 mg	G	1214
	C9245	Injection, romiplostim	G	9245
	C9246	Inj, gadoxetate disodium	G	9246
	C9248	Inj, clevidipine butyrate	G	9248

* Indicates that the drug was paid at a rate determined by the Part B drug CAP methodology (prior to January 1, 2009) while identified as pass-through under the OPPS.

4. Reduction of Transitional Pass-Through Payments for Diagnostic Radiopharmaceuticals To Offset Costs Packaged Into APC Groups

Prior to CY 2008, certain diagnostic radiopharmaceuticals 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 packaged payment for all nonpass-through diagnostic radiopharmaceuticals as ancillary and supportive items and services. Specifically, we packaged payment for all nonpass-through diagnostic radiopharmaceuticals, including those products that would not otherwise have been packaged based solely on the CY 2008 drug packaging threshold, into payment for their associated nuclear medicine procedures. In the CY 2009 OPPS/ASC proposed rule (73 FR 41483), we proposed to continue to package payment in CY 2009 for all nonpass-through diagnostic radiopharmaceuticals as discussed in section V.B.2.c. of this final rule with comment period.

As previously noted, for OPPS pass-through payment purposes, radiopharmaceuticals are considered to be ''drugs.'' 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 OPPS payment amount. Furthermore, transitional pass-through payments for drugs, biologicals, and radiopharmaceuticals under the OPPS are made for a period of at least 2 but not more than 3 years. There are currently no radiopharmaceuticals with pass-through status under the OPPS. For new pass-through radiopharmaceuticals with no ASP information or CAP rate, our proposed and final CY 2009 payment methodology is discussed in section V.A.3. of this final rule with comment period. According to our final policy and consistent with our CY 2008 final policy (72 FR 66755), new pass-through diagnostic radiopharmaceuticals will be paid at ASP+6 percent, while those without ASP information will be paid based on WAC or, if WAC is not available, based on 95 percent of the product's most recently published AWP.

As described in section IV.A.2.a. of the proposed rule and this final rule with comment period regarding pass-through device payment, 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 (the APC device offset amount) to avoid duplicate payment for the device portion of a procedure. This calculation uses calendar year claims data from the period used for the most recent recalibration of the APC payment rates (72 FR 66751 through 66752). We evaluate new pass-through device categories individually to determine if there are device costs packaged into the associated procedural APC payment rate from predecessor devices that resemble the new pass-through device category, suggesting that a device offset amount would be appropriate. On an ongoing basis, through the quarterly transmittals that implement the quarterly OPPS updates, we establish the applicable APC device offset amount, if any, in the same quarter as the eligible pass-through device category is first established. We update device offset amounts annually for eligible pass-through device categories when we recalibrate APC payment rates. We note that we initially implemented the device offset policy in CY 2001 only for pacemakers and neurostimulators but subsequently expanded the offset to other pass-through devices with costs from predecessor devices packaged into the existing APC structure beginning in CY 2002. Since April 2002, we have applied a uniform reduction, the APC device offset amount for the associated procedure, to payment for each of the devices receiving transitional pass-through payments furnished on or after April 1, 2002, and for which we have determined that the pass-through device resembles packaged predecessor devices.

The law specifies two categories of products that are eligible for transitional pass-through payment, specifically implantable devices and drugs and biologicals. Historically, in calculating the APC device offset amount that we have used to evaluate whether a candidate device category for pass-through status meets the cost significance test, we have calculated an amount that reflects the total packaged device costs for all devices that are included on the single bills mapping to the specific APC. This APC device offset amount is then also the amount by which we would reduce the pass-through payment for a device if we determine that the pass-through device resembles packaged predecessor devices.

In the case of drugs and biologicals, we also have historically calculated a single APC drug amount that reflects the total packaged drug (including radiopharmaceutical) costs for all drugs and biologicals that are included on claims mapping to a specific APC. This is the amount that we have used to evaluate whether a candidate drug or biological for pass-through status meets the cost significance test. However, since CY 2008, we have had two major policies for the packaged payment of two categories of nonpass-through drugs and biologicals, specifically those drugs that are always packaged and those drugs that may be packaged. The first group of drugs and biologicals includes diagnostic radiopharmaceuticals and contrast agents, as well as implantable biologicals beginning in CY 2009, which we refer to as ''policy-packaged'' drugs. The second group of drugs and biologicals includes those drugs that are subject to packaging based on their estimated per day costs in relationship to the annual OPPS drug packaging threshold, which we refer to as ''threshold-packaged'' drugs. We are clarifying that, for purposes of determining whether a drug or biological candidate for pass-through status meets the cost significance test, we use the appropriate ''threshold-packaged'' drug amount or ''policy-packaged'' drug amount to assess the criteria, based on the group of drugs to which the pass-through candidate drug belongs. Similarly, for purposes of the radiopharmaceutical offset policy, we utilize the ''policy-packaged'' drug amount to determine the appropriate APC radiopharmaceutical offset. In the case of APCs that contain nuclear medicine procedures, we expect that this ''policy-packaged'' drug amount would consist almost entirely of the costs of diagnostic radiopharmaceuticals. It is this amount by which we would both assess a candidate pass-through diagnostic radiopharmaceutical's cost for purposes of cost significance according to § 419.64(b)(2) and reduce the diagnostic radiopharmaceutical pass-through payment if we determine that the pass-through diagnostic radiopharmaceutical resembles packaged predecessor radiopharmaceuticals.

As we stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41483), because of our proposed CY 2009 packaging policy for diagnostic radiopharmaceuticals, we believe that a payment offset policy, as discussed previously for implantable devices, is now appropriate for diagnostic radiopharmaceuticals approved for pass-through payment status. An APC ''policy-packaged'' offset amount would allow us to avoid duplicate payment for the diagnostic radiopharmaceutical portion of a nuclear medicine procedure by providing a diagnostic radiopharmaceutical pass-through payment that represents the difference between the payment rate for the diagnostic radiopharmaceutical and the packaged predecessor drug costs included in the procedural APC payment for the nuclear medicine procedure. In accordance with section 1833(t)(6)(D)(i) of the Act, the otherwise applicable OPPS payment amount for the diagnostic radiopharmaceutical would roughly be the median cost of the ''policy-packaged'' drug costs for the predecessor radiopharmaceuticals that are packaged into the payment for the nuclear medicine procedure. We indicated in the proposed rule that this APC ''policy-packaged'' drug offset amount, similar to the longstanding device offset policy for payment of implantable devices with pass-through status, would be calculated based on a percentage of the APC payment for a nuclear medicine procedure attributable to the costs of ''policy-packaged'' drugs, including diagnostic radiopharmaceuticals, as reflected in the most recent complete year of hospital outpatient claims data.

Beginning in CY 2009, as we proposed, we would review each new pass-through diagnostic radiopharmaceutical on a case-by-case basis, to determine whether radiopharmaceutical costs associated

with predecessors of the new product are packaged into the existing APC structure for those nuclear medicine procedures with which the new radiopharmaceutical would be used. This methodology is consistent with our current policy for new device categories. Because of the nature of diagnostic radiopharmaceuticals and the small number of nuclear medicine procedures to which they are typically closely linked, we believe that we would usually find costs for predecessor diagnostic radiopharmaceuticals packaged into the existing APC payment for the nuclear medicine procedures associated with the new product. In these cases, we would deduct the uniform, applicable APC ''policy-packaged'' drug offset amount for the associated nuclear medicine procedure from the pass-through payment for the diagnostic radiopharmaceutical. As we proposed, we would establish the pertinent APC offset amounts for newly eligible pass-through diagnostic radiopharmaceuticals quarterly through the transmittals that implement the quarterly OPPS updates and update these offset amounts annually, as needed.

Not all CY 2007 OPPS claims for nuclear medicine procedures include radiolabeled products because radiopharmaceutical claims processing edits were implemented beginning in CY 2008. These claims processing edits require that a radiolabeled product be included on all claims for nuclear medicine procedures to ensure that we capture the full costs of the packaged diagnostic radiopharmaceuticals used for the procedures in future ratesetting. Because our most recent claims data at the time of issuance of the proposed rule did not yet reflect the results of these edits, we proposed to use only those claims that pass the radiopharmaceutical edits to set rates for nuclear medicine procedures in CY 2009, as discussed in section II.A.2.d.(5) of this final rule with comment period. We proposed to use the same claims to calculate the APC ''policy-packaged'' drug offset amounts.

Comment: Some commenters supported the proposed diagnostic radiopharmaceutical offset policy described in the CY 2009 OPPS/ASC proposed rule. These commenters supported CMS' proposal to apply an offset for pass-through diagnostic radiopharmaceuticals as it would ensure that duplicate payment would not be made for diagnostic radiopharmaceuticals by removing the radiopharmaceutical payment amount that is already packaged into the payment for the associated nuclear medicine procedure.

Other commenters were concerned that the pass-through payment amount for diagnostic radiopharmaceuticals would be significantly reduced if the proposed offset policy is applied. Some of these commenters believed that the true costs of currently used diagnostic radiopharmaceuticals are not included in the payment for associated APCs because of hospital billing practices, and that using this unreliable hospital claims information to establish an offset amount would provide inadequate payment for the pass-through diagnostic radiopharmaceutical.

Some commenters suggested calculating a diagnostic radiopharmaceutical offset on a per-nuclear medicine procedure basis. That is, these commenters suggested that the diagnostic radiopharmaceutical offset should be calculated for individual CPT codes, rather than for all procedures assigned to an APC, in order to more specifically identify the diagnostic radiopharmaceutical costs attributable to a specific procedure.

Many commenters asked for further clarification regarding the calculation of the offsets and requested that CMS make the APC radiopharmaceutical offset amounts for the year publicly available for review by stakeholders.

Response: As we stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41483), because of our proposed CY 2009 packaging policy for diagnostic radiopharmaceuticals, we believe that a payment offset policy is appropriate for diagnostic radiopharmaceuticals approved for pass-through payment. An APC ''policy-packaged'' drug offset amount applied to diagnostic radiopharmaceuticals allows us to avoid duplicate payment for the diagnostic radiopharmaceutical portion of a nuclear medicine procedure by providing a diagnostic radiopharmaceutical pass-through payment that represents the difference between the payment rate for the diagnostic radiopharmaceutical and the packaged radiopharmaceutical cost included in the procedural APC payment for the nuclear medicine procedure. As noted above, we distinguish between ''policy-packaged'' drugs and biologicals where a whole category of drugs or biologicals is packaged, regardless of an individual product's cost (such as diagnostic radiopharmaceuticals, contrast agents, and biologicals that are implantable only), from those ''threshold-packaged'' drugs and biologicals that are packaged because of the drug packaging threshold, in order to provide a more accurate offset estimate for diagnostic radiopharmaceutical pass-through purposes.

We do not believe it would be appropriate to calculate the offset amount at the nuclear medicine procedure-specific level because OPPS payment for procedures is provided by APCs that group procedures that share clinical and resource similarities. Therefore, similar to our pass-through device offset policy, we will calculate the offset amount for pass-through diagnostic radiopharmaceuticals at the level of APCs because the APC reflects the OPPS payment for the specific nuclear medicine procedure in which the pass-through diagnostic radiopharmaceutical is used.

The use of a pass-through offset amount is consistent with our current policy for new device categories. Because of the nature of diagnostic radiopharmaceuticals and the small number of nuclear medicine procedures to which they are typically closely linked, contrary to the commenters' concerns, we believe that we will usually find costs for predecessor diagnostic radiopharmaceuticals packaged into the existing APC payment for the nuclear medicine procedures associated with the new product. As we proposed, we will establish the pertinent APC ''policy-packaged'' drug amounts for newly eligible pass-through diagnostic radiopharmaceuticals quarterly through the transmittals that implement the quarterly OPPS updates and update these offset amounts annually, as needed.

We will post annually on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/01_overview.asp*, a file that contains the three offset amounts that will be used for that year for purposes of 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 provide, for every OPPS clinical APC, the amounts and percentages of APC payment associated with packaged implantable devices, ''policy-packaged'' drugs and biologicals, and ''threshold-packaged'' drugs and biologicals.

Comment: Several commenters recommended that CMS provide extensive education for Medicare contractors (fiscal intermediaries and A/B MACs) on how the offset should be applied and how payment should be made for pass-through diagnostic radiopharmaceuticals. One commenter requested that CMS provide hospital-specific education in order to prevent

hospitals from charging beneficiaries for any perceived difference in payment as a result of the offset, especially in situations where the beneficiary has been given an Advance Beneficiary Notice (ABN).

Response: Our standard process is to release instructions in the January quarterly transmittal related to the updated OPPS policies finalized in the annual final rule with comment period. We will continue to provide instructions to our Medicare contractors on our policy changes in this manner, including the offset policy for diagnostic radiopharmaceuticals with pass-through status included in this final rule with comment period. Determination of offset eligibility and payment is determined in the OPPS PRICER, the pricing utility for OPPS payment. Medicare contractors have been successfully applying the offset policy through implementation of the OPPS PRICER for pass-through implantable devices for many years, and we do not expect that contractors will have difficulty providing appropriate payment for those pass-through diagnostic radiopharmaceuticals for which we have identified a drug offset amount.

In addition, we remind readers that packaged items and services are covered and paid under the OPPS. Hospitals may only provide an ABN when the hospital expects that the service provided to the beneficiary will not be covered under any Medicare benefit category. Although hospitals do not receive separate payment from Medicare for packaged items and supplies, hospitals may not bill beneficiaries separately for any packaged items and supplies because those costs are recognized and paid within the 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 payment for packaged services. We believe that the vast majority of hospitals understand the correct use of ABNs, and that situations such as the one suggested the commenter would be rare. For more information on mandatory and voluntary uses of ABNs, we refer readers to the Medicare Claims Processing Manual, Pub. 100–4, Chapter 30, Sections 50.3.1 and 50.3.2.

Comment: One commenter requested that CMS not apply a pass-through payment offset to pass-through contrast agents unless proper notice was provided and there was an opportunity for public comment. The commenter noted that the offset methodology would likely be unnecessary for contrast agents, as most contrast agents have per day cost estimates of under $60 and, therefore, are not likely to pass the cost significance test required for pass-through drug status.

Response: We believe the commenter misunderstood our proposed offset policy. We did not make a proposal to apply a pass-through offset methodology for contrast agents, and we are not implementing an offset for pass-through contrast agents for CY 2009.

After consideration of the public comments received, we are finalizing our proposal to apply an offset methodology to diagnostic radiopharmaceuticals that are granted pass-through status for CY 2009 without modification. Specifically, the APC ''policy-packaged'' drug offset fraction for APCs containing nuclear medicine procedures in CY 2009 is: 1 minus (the cost from single procedure claims in the APC that pass nuclear medicine procedure-to-radiolabeled product edits after removing the costs for ''policy-packaged'' drugs and biologicals divided by the cost from single procedure claims in the APC that pass the claims processing edits). To determine the actual APC offset amount for diagnostic radiopharmaceuticals granted pass-through status in CY 2009, we multiply the resulting fraction by the CY 2009 APC payment amount for the procedure with which the new diagnostic radiopharmaceutical is used and, accordingly, reduce the APC payment associated with the transitional pass-through diagnostic radiopharmaceutical by this amount.

We will post annually on the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/01_overview.asp*, a file that contains the three offset amounts that will be used for that year for purposes of 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 provide, for every OPPS clinical APC, the amounts and percentages of APC payment associated with packaged implantable devices, ''policy-packaged'' drugs and biologicals, and ''threshold-packaged'' drugs and biologicals.

Table 25 displays the APCs to which nuclear medicine procedures are assigned in CY 2009 and for which we expect that an APC offset could be applicable in the case of new diagnostic radiopharmaceuticals with pass-through status.

TABLE 25—APCS TO WHICH NUCLEAR MEDICINE PROCEDURES ARE ASSIGNED FOR CY 2009

Final CY 2009 APC	CY 2009 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.
0395	GI Tract Imaging.
0396	Bone Imaging.
0397	Vascular Imaging.
0398	Level I Cardiac Imaging.
0400	Hematopoietic Imaging.
0401	Level I Pulmonary Imaging.
0402	Level II Nervous System Imaging.
0403	Level I Nervous System Imaging.
0404	Renal and Genitourinary Studies.
0406	Level I Tumor/Infection Imaging.
0408	Level III Tumor/Infection Imaging.
0414	Level II Tumor/Infection Imaging.

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

1. Background

Under the CY 2008 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 from Medicare 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 Public Law 108–173, sets 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 CY 2008, the packaging threshold for drugs, biologicals, and radiopharmaceuticals that are not new and do not have pass-through status was established at $60. The methodology used to establish the $55 threshold for CY 2007, the $60 threshold for CY 2008, and our proposed and final approach for CY 2009 are discussed in more detail in section V.B.2.b. of this final rule with comment period.

In addition, since CY 2005, we have provided an exemption to this packaging determination for oral and injectable 5HT3 anti-emetic products. We discuss in section V.B.2. of this final rule with comment period our proposed and final CY 2009 payment policy for these anti-emetic products.

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

a. Background

As indicated above, 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 Public Law 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)), for CY 2008 we set the packaging threshold for establishing separate APCs for drugs and biologicals at $60.

In addition, in CY 2008 we began distinguishing between diagnostic and therapeutic radiopharmaceuticals for payment purposes under the OPPS. We finalized a policy that identified diagnostic radiopharmaceuticals as those Level II HCPCS codes that include the term ''diagnostic'' along with a radiopharmaceutical in their long code descriptors. Therapeutic radiopharmaceuticals were identified as those Level II HCPCS codes that have the term ''therapeutic'' along with a radiopharmaceutical in their long code descriptors. We again noted that all radiopharmaceutical products fall into one category or the other; their use as a diagnostic radiopharmaceutical or therapeutic radiopharmaceutical is mutually exclusive.

b. Drugs, Biologicals, and Therapeutic Radiopharmaceuticals

Following the CY 2007 methodology for CY 2009, 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 2009 and again rounded the resulting dollar amount ($61.25) to the nearest $5 increment, which yielded a figure of $60. 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, in the proposed rule, we proposed a packaging threshold for CY 2009 of $60. During its March 2008 meeting, the APC Panel made a recommendation supporting CMS' current methodology of adjusting the threshold dollar amount for packaging drugs and biologicals on the basis of the PPI for prescription drugs. (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).)

For the fourth year, we proposed to continue exempting the oral and injectable forms of 5HT3 anti-emetics products from packaging, thereby making separate payment for all of these products. As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65779 through 65780), it is our understanding that chemotherapy is very difficult for many patients to tolerate, as the side effects are often debilitating. In order for Medicare beneficiaries to achieve the maximum therapeutic benefit from thermotherapy and other therapies with side effects of nausea and vomiting, anti-emetic use is often an integral part of the treatment regiment. In the proposed rule, we stated our belief that we should continue to ensure that Medicare payment rules do not impede a beneficiary's access to the particular anti-emetic that is most effective for him or her, as determined by the beneficiary and the treating physician.

Comment: Several commenters supported CMS' proposal to maintain the packaging threshold at $60 for CY 2009. One commenter expressed concern that annual increases may limit patient access to drugs in the HOPD setting.

A few commenters recommended a variety of alternatives for CMS to consider, including: (1) Eliminating the drug packaging threshold and provide separate payment for all drugs; (2) permanently establishing the packaging threshold at $60; or (3) not increasing the drug packaging threshold for CY 2009. Some commenters believed that eliminating the drug packaging threshold would allow for parity in drug payment between the HOPD setting and the physician's office setting and, therefore, would provide transparency for beneficiaries who are comparing the costs of care between the two settings. In addition, these commenters claimed that eliminating the drug packaging threshold would increases the accuracy of hospital claims by providing an incentive to hospitals to correctly code for all drugs. Several commenters noted that the current packaging threshold discourages hospitals from using less costly packaged drugs because these drugs are not paid separately in the HOPD setting. Other comments believed that setting a permanent drug packaging threshold would eliminate the potential for incremental changes in the threshold

that could adversely affect hospital payment.

Response: As fully discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66757–66758), we continue to believe that unpackaging payment for all drugs, biologicals, and radiopharmaceuticals is inconsistent with the concept of a prospective payment system and that such a change could create an additional reporting burden for hospitals. The OPPS and the MPFS that applies to physician's office services are fundamentally different payment systems with essential differences in their payment policies and structure. Specifically, the OPPS is a prospective payment system, based on the concept of payment for groups of services that share clinical and resource characteristics. Payment is made under the OPPS according to prospectively established payment rates that are related to the relative costs of hospital resources for services. The MPFS is a fee schedule that generally provides payment for each individual component of a service. Consistent with the MPFS approach, separate payment is made for each drug provided in the physician's office, but the OPPS packages payment for certain drugs into the associated procedure payments for the APC group. Because of the different payment policies, differences in the degrees of packaged payment and separate payment between these two systems are only to be expected. In general, we do not believe that our packaging methodology under the OPPS results in limited beneficiary access to drug administration services because packaging is a fundamental component of a prospective payment system that accounts for the cost of certain items and services in larger payment bundles, recognizing that some clinical cases may be more costly and others less costly but that, on average, OPPS payment is appropriate for the services provided.

We note that, in CYs 2005 and 2006, the statutorily mandated drug packaging threshold was set at $50, and we believe that it is currently appropriate to continue a modest drug packaging threshold for the CY 2009 OPPS for the reasons set forth below. As stated in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68086), we believe that packaging certain items is a fundamental component of a prospective payment system, that packaging these items does not lead to beneficiary access issues and does not create a problematic site of service differential, that the packaging threshold is reasonable based on the initial establishment in law of a $50 threshold for the CY 2005 OPPS, that updating the $50 threshold is consistent with industry and government practices, and that the PPI for prescription preparations is an appropriate mechanism to gauge Part B drug inflation. Therefore, because of our continued belief that packaging is a fundamental component of a prospective payment system that contributes to important flexibility and efficiency in the delivery of high quality hospital outpatient services, we are not adopting the commenters' recommendations to pay separately for all drugs, biologicals, and radiopharmaceuticals for CY 2009 or to eliminate or to freeze the packaging threshold at $60.

For purposes of this final rule with comment period, we again followed the CY 2007 methodology for CY 2009 and 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 2009 and again rounded the resulting dollar amount ($61.95) to the nearest $5 increment, which continued to yield a figure of $60. In performing this calculation, we used the most up-to-date forecasted, quarterly PPI estimates from CMS' OACT.

After consideration of the public comments received, we are accepting the March 2008 APC Panel recommendation to continue to use our CY 2007 methodology of updating annually the OPPS packaging threshold for drugs and biologicals by the PPI for prescription drugs, and we are finalizing our CY 2009 proposed packaging threshold of $60, without modification, calculated according to the threshold update methodology that we began applying in CY 2007.

Comment: Several commenters supported the proposal to continue to exempt the oral and injectable forms of 5HT3 anti-emetic products that were listed in Table 23 of the proposed rule (reprinted as Table 26 below) from packaging, thereby making separate payment for all of the 5HT3 anti-emetic products.

In addition, several commenters requested that CMS apply the same principle to other groups of drugs in order to equalize payment methodologies across drugs in the same clinical group. One commenter suggested that CMS institute a similar policy for anticoagulant therapies provided in the HOPD. This commenter noted that there are several drug treatments for deep vein thrombosis, and that one drug treatment is paid separately while others are packaged. The commenter was concerned that these different payment methodologies provide hospitals an incentive to use the separately paid drugs, although the commenter noted that treatments are not interchangeable and that benefits vary by patient.

Another commenter suggested that CMS expand the packaging threshold exemption to antineoplastic agents and other anticancer therapeutic agents. The commenter believed that anticancer agents, as a class, are not appropriate for packaging because of the toxicity, side effects, interactions with other drugs, and level of patient specificity associated with these therapies. Therefore, the commenter requested that CMS not apply the drug packaging threshold for anticancer agents and provide separate payment for all of these products in CY 2009.

Response: We appreciate the support for our proposal to continue exempting the 5HT3 anti-emetic products from our packaging determination. We note that as we continue to explore the possibility of additional encounter-based or episode-based payment in future years, and as we first discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66757), we may consider additional options for packaging drug payment in the future. We also note that if we were to increase the OPPS drug packaging threshold, we might no longer need to make a special exemption for these products because all of the products might be packaged under such an approach. Similarly, a higher drug packaging threshold could eliminate existing disparities in payment methodologies for other drug groups and provide similar methods of payment across items in a group.

Nevertheless, while we may be interested in alternative threshold methodologies for future ratesetting purposes, we realize that there are existing situations where drugs in a particular category vary in their payment treatment under the OPPS, with some drugs packaged and other separately paid. We believe the challenges associated with categorizing drugs to assess them for difference in their OPPS payment methodologies are significant, and we are not convinced that ensuring the same payment treatment for all drugs in other drug categories is essential at this time, beyond the proposal we made for 5HT3 antiemetics. Therefore, we do not believe that it would be appropriate at this time to take any additional steps to ensure that all drugs in a specific category, including anticoagulants and antineoplastic agents, are all separately paid (or, alternatively, are all packaged), as requested by some commenters.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to again exempt the oral and injectable forms of 5HT3 antiemetic products listed in Table 26 below from our drug packaging methodology for CY 2009.

TABLE 26—ANTI-EMETICS EXEMPTED FROM CY 2009 OPPS DRUG PACKAGING THRESHOLD

CY 2009 HCPCS code	CY 2009 short descriptor
J1260	Dolasetron mesylate.
J1626	Granisetron hcl injection.
J2405	Ondansetron hcl injection.
J2469	Palonosetron hcl.
Q0166	Granisetron hcl 1 mg oral.
Q0179	Ondansetron hcl 8 mg oral.
Q0180	Dolasetron mesylate oral.

To determine their CY 2009 packaging status for the proposed rule, we calculated the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals that had a HCPCS code in CY 2007 and were paid (via packaged or separate payment) under the OPPS using claims data from January 1, 2007, to December 31, 2007. In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their packaging status in CY 2009, as we proposed, 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 2009 proposed rule per day costs, we used an estimated payment rate for each drug and biological of ASP+4 percent (which is the payment rate we proposed for separately payable drugs and biologicals in CY 2009, as discussed in more detail in section V.B.3.b. of this final rule with comment period). We used the manufacturer submitted ASP data from the fourth quarter of CY 2007 (data that were used for payment purposes in the physician's office setting, effective April 1, 2008) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2009, we proposed to use payment rates based on the ASP data from the fourth quarter of CY 2007 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to the proposed rule because these were the most recent data available for use at the time of development of the proposed rule. These data were also the basis for drug payments in the physician's office setting, effective April 1, 2008. For items that did not have an ASP-based payment rate, we used their mean unit cost derived from the CY 2007 hospital claims data to determine their proposed per day cost. We proposed to package items with a per day cost less than or equal to $60 and proposed to identify items with a per day cost greater than $60 as separately payable. Consistent with our past practice, we crosswalked historical OPPS claims data from the CY 2007 HCPCS codes that were reported to the CY 2008 HCPCS codes that we displayed in Addendum B to the proposed rule for payment in CY 2009.

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 drugs, biologicals, and radiopharmaceuticals for the final rule with comment period. We note that it is also our policy to make an annual packaging determination only when we develop the OPPS/ASC final rule for the update year. As indicated in the proposed rule (73 FR 41485), only items that are identified as separately payable in this final rule with comment period are subject to quarterly updates. For our calculation of per day costs of drugs and biologicals in this CY 2009 OPPS/ASC final rule with comment period, as we proposed, we used ASP data from the first quarter of CY 2008, 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, 2008, along with updated hospital claims data from CY 2007. As proposed, we note that we also used these data for budget neutrality estimates and impact analyses for this CY 2009 OPPS/ASC final rule with comment period. As proposed, payment rates for separately payable drugs and biologicals included in Addenda A and B to this final rule with comment period are based on ASP data from the second quarter of CY 2008, 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, 2008. Furthermore, as proposed, these rates will be updated in the January 2009 OPPS update, based on the most recent ASP data to be used for physician's office and OPPS payment as of January 1, 2009.

We note that we proposed to use hospital claims data to establish the packaging status of therapeutic radiopharmaceuticals in our CY 2009 OPPS/ASC proposed rule. As discussed previously, after issuance of the CY 2009 OPPS/ASC proposed rule, Public Law 110–275 was enacted and, as a result, we are required to provide payment for therapeutic radiopharmaceuticals at charges adjusted to cost for CY 2009. Therefore, we are not using hospital claims data to determine the packaging status of therapeutic radiopharmaceuticals based on their per day costs. Rather, all therapeutic radiopharmaceuticals will be paid separately in CY 2009 at hospital charges adjusted to cost.

Consequently, the packaging status for some drugs and biologicals in this CY 2009 OPPS/ASC final rule with comment period using the updated data is different from the same drug's packaging status determined based on the data used for the proposed rule. Under such circumstances, as we proposed, we are applying the following policies to these drugs and biologicals whose relationship to the $60 threshold changed based on the final updated data:

- Drugs and biologicals that were paid separately in CY 2008 and that were proposed for separate payment in CY 2009, and then have per day costs equal to or less than $60, based on the updated ASPs and hospital claims data used for this CY 2009 final rule with comment period, will continue to receive separate payment in CY 2009.
- Drugs and biologicals that were packaged in CY 2008 and that were proposed for separate payment in CY 2009, and then have per day costs equal to or less than $60, based on the updated ASPs and hospital claims data used for this CY 2009 final rule with comment period, will remain packaged in CY 2009.
- Drugs and biologicals for which we proposed packaged payment in CY 2009 but then have per day costs greater than $60, based on the updated ASPs and hospital claims data used for this CY 2009 final rule with comment period, will receive separate payment in CY 2009.

We note that HCPCS code J8510 (Busulfan; oral, 2 mg) was paid separately in CY 2008 and was proposed for separate payment in CY 2009, but had a final per day cost of approximately $57, which is less than the $60 threshold, based on the updated ASPs and hospital claims data used for this CY 2009 final rule with comment period. HCPCS code J8510 will continue to receive separate payment in CY 2009 according to the established methodology set forth above.

In addition, there were several drugs and biologicals that we proposed to package in the proposed rule and that now have per day costs greater than $60 using updated ASPs and all of the

hospital claims data from CY 2007 used for this final rule with comment period. In accordance with our established policy for such cases, for CY 2009 we will pay for these drugs and biologicals separately. Table 27 lists the drugs and biologicals that were proposed as packaged, but that will be paid separately in CY 2009. We note that for CY 2009, the CMS HCPCS Workgroup has established two new codes for the products that were previously assigned to HCPCS code J7341 (Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter) in CY 2008. HCPCS code J7341 was proposed to be packaged for CY 2009 but updated final rule data indicate a per day cost of over the $60 drug packaging threshold. As is our standard methodology, we are establishing separate payment for both of the new CY 2009 HCPCS codes, Q4102 (Skin substitute, Oasis wound matrix, per square centimeter) and Q4103 (Skin substitute, Oasis burn matrix, per square centimeter), as their predecessor code would have been separately payable in CY 2009.

TABLE 27—DRUGS AND BIOLOGICALS PROPOSED AS PACKAGED BUT WITH FINAL PER DAY COSTS ABOVE $60, FOR WHICH SEPARATE PAYMENT WILL BE MADE IN CY 2009

CY 2009 HCPCS code	CY 2009 short descriptor
J0630	Calcitonin salmon injection.
J1212	Dimethyl sulfoxide 50% 50 ML.
J2513	Pentastarch 10% solution.
J2515	Pentobarbital sodium inj.
J2805	Sincalide injection.
J2940	Somatrem injection.
J2995	Inj streptokinase /250000 IU.
J3350	Urea injection.
J3473	Hyaluronidase recombinant.
Q4102	Oasis wound matrix skin sub.
Q4103	Oasis burn matrix skin sub.
J8650	Nabilone oral.
J9270	Plicamycin (mithramycin) inj.
J9280	Mitomycin 5 MG inj.
J9290	Mitomycin 20 MG inj.
J9291	Mitomycin 40 MG inj.
J9357	Valrubicin injection.

c. Payment for Diagnostic Radiopharmaceuticals and Contrast Agents

As established in the CY 2008 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. 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.

During the March 2008 meeting of the APC Panel, the APC Panel recommended that CMS continue to package payment for diagnostic radiopharmaceuticals for CY 2009 and present data at the first CY 2009 meeting on the usage and frequency, geographic distribution, and size and type of hospitals performing studies using radioisotopes in order to ensure that access is preserved for Medicare beneficiaries. We discuss our response to these APC Panel recommendations along with public comments we received in response to our proposed rule below.

Comment: Several commenters disagreed with the proposal to distinguish between diagnostic and therapeutic radiopharmaceuticals for payment purposes under the OPPS. Some of these commenters noted that CMS' identification of HCPCS codes A9542 (Indium In-111 ibritumomab ituxetan, diagnostic, per study dose, up to 5 millicuries) and A9544 (Iodine I–131 tositumomab, diagnostic, per study dose) as diagnostic radiopharmaceuticals was inappropriate because these radiopharmaceuticals function as dosimetric radiopharmaceuticals, and they have higher than average costs associated with their acquisition and significant compounding costs as compared to other nuclear medicine imaging agents. A few commenters explained that these are radiopharmaceutical products that are used as part of a therapeutic regimen and, therefore, should be considered therapeutic for OPPS payment purposes.

Several commenters disagreed with CMS' statement that radiopharmaceuticals are either diagnostic or therapeutic, and that they are mutually exclusive. These commenters noted that some products serve as ''theranostics'' and can be used both as a diagnostic and a therapeutic radiopharmaceutical.

Response: As discussed above, for the CY 2008 OPPS/ASC final rule with comment period and the CY 2009 OPPS/ASC proposed rule, we classified each radiopharmaceutical into one of two groups according to whether its long descriptor contained the term ''diagnostic'' or ''therapeutic.'' HCPCS codes A9542 and A9544 both contain the term ''diagnostic'' in their long code descriptors. Therefore, according to this methodology, we continue to classify them as diagnostic for the purposes of OPPS payment. While we understand that these items are provided in conjunction with additional supplies, imaging tests, and therapeutic radiopharmaceuticals for patients already diagnosed with cancer, we continue to believe that the purpose of administering the products described by HCPCS codes A9542 and A9544 is diagnostic in nature. As we first stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66641), we continue to believe that HCPCS codes A9542 and A9544 are diagnostic radiopharmaceuticals. While they are not used to diagnose disease, they are used to determine whether future therapeutic services would be beneficial to the patient and to determine how to proceed with therapy. While a group of associated services may be considered a therapeutic regimen by some commenters, HCPCS codes A9542 and A9544 are provided in conjunction with a series of nuclear medicine imaging scans. Many nuclear medicine studies using diagnostic radiopharmaceuticals are provided to patients who already have an established diagnosis. We do not consider HCPCS codes A9542 and A9544 to be therapeutic because these items are provided for the purpose of a diagnostic imaging procedure, and are used to identify the proper dose of the therapeutic agent to be provided at a later time.

Commenters who indicated that ''theranostic'' products can be used as either diagnostic or therapeutic radiopharmaceuticals failed to provide specific product names or HCPCS codes for these products. We have been unable to identify any of the products that the commenters were referring to, and we note that all radiopharmaceuticals with HCPCS codes currently have either ''diagnostic'' or ''therapeutic'' in their

long code descriptors. We are aware that, in some cases, a patient may receive a therapeutic radiopharmaceutical for treatment of disease and the patient may not then require further administration of a diagnostic radiopharmaceutical for a nuclear medicine study because the patient's body already contains sufficient radioactivity. However, in this case, we would consider the original radiopharmaceutical to be a therapeutic radiopharmaceutical because it was administered to treat the patient's disease and not mainly for purposes of the nuclear medicine study.

Comment: Several commenters objected to CMS' proposal to package payment for all diagnostic radiopharmaceuticals and contrast agents in CY 2009. A number of commenters stated that diagnostic radiopharmaceuticals and contrast agents with per day costs over the proposed OPPS drug packaging threshold are defined as specified covered outpatient drugs (SCODs) and, therefore, should be assigned separate APC payments. In particular, the commenters questioned CMS' authority to classify groups of drugs, such as diagnostic radiopharmaceuticals and contrast agents, and implement packaging and payment policies that do not reflect their status as SCODs. In addition, the commenters objected to the proposal to package payment for diagnostic radiopharmaceuticals and contrast agents because, as SCODs, the commenters believed these products were required by statute to be paid at average acquisition cost. The commenters explained that, when several different diagnostic radiopharmaceuticals or contrast agents may be used for a particular procedure, the costs of those diagnostic radiopharmaceuticals or contrast agents are averaged together and added to the cost for the procedure in order to determine the payment rate for the associated procedural APC. Therefore, the commenters argued that the amount added to the procedure cost through packaging, representing the cost of the diagnostic radiopharmaceutical or contrast agent, did not reflect the average acquisition cost of any one particular item but, rather, reflected the average cost of whatever items may have been used with that particular procedure.

Response: As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66767) and in the CY 2009 OPPS/ASC proposed rule (73 FR 41486), we believe diagnostic radiopharmaceuticals and contrast agents are different from other SCODs for several reasons. We note that the statutorily required OPPS drug packaging threshold has expired, and we continue to believe that diagnostic radiopharmaceuticals and contrast agents function effectively as supplies that enable the provision of an independent service, rather than serving themselves as the therapeutic modality. We packaged their payment in CY 2008 as ancillary and supportive services in order to provide incentives for greater efficiency and to provide hospitals with additional flexibility in managing their resources. We note that we currently classify different groups of drugs for specific payment purposes, as evidenced by our policy regarding the oral and injectable forms of the 5HT3 anti-emetics and our drug packaging threshold.

Although our final CY 2008 policy that we are continuing for CY 2009, as discussed below, packages payment for all diagnostic radiopharmaceuticals and contrast agents into the payment for their associated procedures, we will continue to provide payment for these items in CY 2009 based on a proxy for average acquisition cost. We believe that the line-item estimated cost for a diagnostic radiopharmaceutical or contrast agent in our claims data is a reasonable approximation of average acquisition and preparation and handling costs for diagnostic radiopharmaceuticals or contrast agents, respectively, because, as we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66766), we believe that hospitals have adapted to the CY 2006 coding changes for radiopharmaceuticals and responded to our instructions to include charges for radiopharmaceutical handling in their charges for the radiopharmaceutical products. Further, because the standard OPPS packaging methodology packages the total estimated cost for each radiopharmaceutical or contrast agent on each claim (including the full range of costs observed on the claims) with the cost of associated procedures for ratesetting, this packaging approach is consistent with considering the average cost for radiopharmaceuticals or contrast agents, rather than the median cost.

We further note that these drugs, biologicals, or radiopharmaceuticals for which we have not established a separate APC and, therefore, for which payment would be packaged rather than separately provided under the OPPS, could be considered to not be SCODs. Similarly, drugs and biologicals with mean per day costs of less than $60 that are packaged and for which a separate APC has not been established also would not be SCODs. This reading is consistent with our final payment policy whereby we package payment for diagnostic radiopharmaceuticals and contrast agents and provide payment for these products through payment for their associated procedures.

Comment: Several commenters recommended various methodologies for CMS to consider in the development of alternate payment mechanisms for identifying associated costs and providing separate payment for diagnostic radiopharmaceuticals. Some commenters supported the ASP methodology for payment of nonpass-through diagnostic radiopharmaceuticals and noted that it would be inconsistent for CMS to allow payment for diagnostic radiopharmaceuticals that have pass-through status based on the ASP methodology, and then, after the diagnostic radiopharmaceutical's pass-through payment status has expired, package the costs present on hospital claims data. The commenters believed that the ASP methodology would be more reflective of actual diagnostic radiopharmaceutical costs and would not be subject to the billing inconsistencies that are present in hospital claims data. Therefore, the commenters concluded that it would be illogical to transition from an accurate methodology to estimate hospital costs (such as the ASP methodology) to a less accurate methodology (based on hospital claims data) once a product is no longer eligible for pass-through payment.

Some commenters were not supportive of the ASP methodology because they indicated that some manufacturers would be unable to report patient-specific doses based on the HCPCS code descriptor. The commenters recommended that CMS establish a methodology that is similar to the ASP methodology but that uses alternative data sources (such as nuclear pharmacies) that could be used to calculate an ASP-like figure for all radiopharmaceuticals.

Other commenters suggested that CMS establish diagnostic radiopharmaceutical and nuclear medicine procedure composite APCs that group specific diagnostic radiopharmaceuticals with specific nuclear medicine procedures. The commenters stated that diagnostic radiopharmaceuticals are not interchangeable and carry high costs because hospitals have little or no flexibility in determining the diagnostic radiopharmaceutical that they must purchase because of product specificity and patient needs, and therefore have

little ability to achieve efficiency. The commenters believed that payment based on individualized combinations of these items and services would provide more accurate payment for the diagnostic radiopharmaceutical component of the service, and would decrease the payment variation (both overpayment and underpayment) for nuclear medicine procedures performed by hospitals that occurs under the current packaging methodology.

Several commenters expressed an interest in the establishment of a composite APC for CPT codes 78802 (Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, single day imaging) or 78804 (Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring two or more days imaging) when billed with either HCPCS code A9542 (Indium In-111 ibritumomab ituxetan, diagnostic, per study dose, up to 5 millicuries) or A9544 (Iodine I–131 tositumomab, diagnostic, per study dose).

Response: We again note that there are currently no radiopharmaceuticals with pass-through status, nor do we have any pass-through applications for radiopharmaceuticals under review at the time of this final rule with comment period. While we understand that the commenters' request for the continued use of ASP data for purposes of packaging costs after a diagnostic radiopharmaceutical's pass-through payment period has ended, based on their belief that ASP data are more accurate than hospital claims data, we fully expect that hospitals have the ability to identify and set charges for any new diagnostic radiopharmaceutical product accurately during its 2 to 3 year pass-through time period while the product has the potential of being paid based on ASP. Packaging hospital costs based on hospital claims data is how all the costs of all packaged items are factored into payment rates for associated procedures under the OPPS. We believe that the costs reported on claims, as determined by hospitals, are the most appropriate representation of the costs of diagnostic radiopharmaceuticals that should be packaged into payment for the associated nuclear medicine procedures.

We further note that some commenters continued to report that not all manufacturers would be able to submit ASP data through the established ASP reporting methodology. Therefore, if we were to use ASP data to package the costs of some diagnostic radiopharmaceuticals, but use hospital claims data for others, our methodologies for packaging the costs of diagnostic radiopharmaceuticals into their associated nuclear medicine procedures would be inconsistent among nuclear medicine procedures. The foundation of a system of relative weights is the relativity of the costs of all services to one another, as derived from a standardized system that uses standardized inputs and a consistent methodology. Adoption of a ratesetting methodology for certain APCs containing nuclear medicine procedures that is different from the standard APC ratesetting methodology would undermine this relativity. For this reason, we believe it would not be appropriate to use external pricing information in place of the costs derived from the claims and Medicare cost report data because we believe that to do so would distort the relativity that is so fundamental to the integrity of the OPPS.

We recognize that radiopharmaceuticals are specialized products that have unique costs associated with them. However, we believe that the costs are reflected in the charges that hospitals set for them and in the Medicare cost report where the full costs and charges associated with the services are reported. Therefore, the packaged costs of diagnostic radiopharmaceuticals are calculated like any other OPPS costs and packaged into the cost of the nuclear medicine service to which they are ancillary and supportive. This methodology is the basis for the payment of nuclear medicine procedures in the same way that other packaged costs contribute to the payment rates for the services to which they are an integral part.

We do not agree with the commenters that it would be appropriate to create composite APCs for combinations of certain diagnostic radiopharmaceuticals and nuclear medicine procedures. We discuss our response to these public comments in detail in section II.A.2.d.(5) of this final rule with comment period.

Comment: Some commenters believed that packaging diagnostic radiopharmaceuticals would undermine the clinical and resource homogeneity of the nuclear medicine APCs, especially the cardiac imaging APCs, resulting in 2 times violations.

Response: We agree that packaging the costs of ancillary and supportive services into the median cost of an independent service can change the median cost for that service and could result in 2 times violations. However, we disagree that we should refrain from packaging payment for ancillary and supportive items into the payment for the service in which they are used in order to prevent the occurrence of 2 times violations. Instead, we believe that we should reconfigure APCs when necessary to resolve 2 times violations where they occur. Because we have traditionally paid for a service package under the OPPS as represented by a HCPCS code for the major procedure that is assigned to an APC group for payment, we assess the applicability of the 2 times rule to services at the HCPCS code level, not at a more specific level based on the individual diagnostic radiopharmaceuticals that may be utilized in a service reported with a single HCPCS code. If the use of a very expensive diagnostic radiopharmaceutical in a clinical scenario causes a specific procedure to be much more expensive for the hospital than the APC payment, we consider such a case to be the natural consequence of a prospective payment system that anticipates that some cases will be more costly and others less costly than the procedure payment. In addition, very high cost cases could be eligible for outlier payment. As we note elsewhere in this final rule with comment period, decisions about packaging and bundling payment involve a balance between ensuring some separate payment for individual services and establishing incentives for efficiency through larger units of payment. In the case of diagnostic radiopharmaceuticals, these products are part of the OPPS payment package for the procedures in which they are used.

Comment: A few commenters requested that CMS specify the methodology used to package diagnostic radiopharmaceuticals and contrast agents into their associated procedures. Some of these commenters also requested that CMS release data that indicate that there is a direct relationship between the cost of diagnostic radiopharmaceuticals or contrast agents and the resulting increase in the associated procedural APC payment rate. Other commenters expressed disappointment that CMS was not proposing any additional payment for compounding and handling costs for diagnostic radiopharmaceuticals. The commenters pointed out that compounding costs were especially high for products described by HCPCS codes A9542 and A9544.

Response: To set the payment for nuclear medicine procedures that require a radiolabeled product (usually a diagnostic radiopharmaceutical), we selected claims that contained a

radiolabeled product and used these selected claims (rather than all claims for these procedures) to set the median costs for nuclear medicine procedures so that we could ensure that the costs of the radiopharmaceutical were packaged into the median cost for the procedure. This methodology is discussed in detail in section II.A.2.d.(5) of this final rule with comment period. As we indicated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66639), beginning on January 1, 2008, we implemented claims processing edits for procedures that we believe require a radiolabeled product, and we return to the provider to correct claims for nuclear medicine procedure that do not include a radiolabeled product. Therefore, for the CY 2010 OPPS our claims data should include a radiolabeled product on all of the nuclear medicine procedure claims. As discussed below, we have not implemented claims processing edits that require the inclusion of contrast agent HCPCS codes on claims for studies provided with contrast but we are interested in public comment on this topic.

According to our usual OPPS methodology, we package the costs of packaged items and services into the costs of the associated procedures on single and ''pseudo'' claims for those procedures. In the case of packaged diagnostic radiopharmaceuticals and contrast agents, in most cases packaging would be into the costs of associated nuclear medicine procedures and radiological studies performed with contrast, respectively. With respect to the request for data for these services, we make available a considerable amount of data for public analysis each year and, while we are not developing and providing the detailed information that commenters requested, we provide the public use files of claims and a detailed narrative description of our data process that the public can use to perform any desired analyses. In addition, we believe that the commenters must examine the data themselves when developing their comments on the OPPS/ASC proposed rules. We note that several commenters submitted detailed analyses of claims for packaged services of particular interest to them which we believe demonstrates that commenters are clearly able to perform meaningful analyses using the public claims data that we routinely make available.

With respect to the issue of payment for compounding and handling of radiopharmaceutical and contrast agents, in particular the products described by HCPCS codes A9542 and A9544, we believe that the costs derived from the application of the most specific CCR to the charges for these products produce an estimated cost that includes the costs of compounding and handling of the products. We have instructed hospitals to include the charge for radiopharmaceutical handling and compounding in their charge for the radiopharmaceutical in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68096), and hospitals have told us that they do so. Moreover, the costs reported in the cost report are for both the acquisition costs for the products and the costs of compounding and handling for both inexpensive and expensive products. Therefore, we believe that the estimated cost derived by the application of the CCR to the charge for the product results in an estimated cost that includes both the product acquisition cost and the compounding and handling costs of the product and that this is true regardless of the cost of the product.

Comment: Some commenters expressed frustration with the I/OCE claims processing edits implemented in CY 2008 for nuclear medicine procedures that require a radiolabeled product in order for the claim to process to payment. The commenters reported that it has been administratively burdensome for hospitals to cope with these edits and conform claims to these requirements, and they noted that patient access to nuclear medicine procedures has been adversely affected.

Specifically, some commenters observed that there are situations that occur in the hospital outpatient setting that are not accounted for in these edits. For example, hospitals sometimes provide a nuclear medicine imaging service to a beneficiary who has been given a radiopharmaceutical in another location, such as in a physician's office. The commenters explained that, at this time, there is no way for these outpatient nuclear medicine procedure claims to process to payment. The commenters requested that CMS create a modifier or Level II HCPCS code so that hospitals could indicate that special circumstances applied, and that a radiolabeled product was not provided in the HOPD setting, thereby allowing payment for the nuclear medicine service.

Other commenters requested that CMS implement I/OCE edits for contrast agents and imaging studies provided with contrast, similar to the nuclear medicine procedure-to-radiolabeled product edits. The commenters believed that requiring hospitals to specifically report a contrast agent HCPCS code when performing an imaging study with contrast would result in more accurate claims data that fully reflected the costs of contrast agents.

Finally, some commenters requested that CMS only use claims with diagnostic radiopharmaceuticals, or contrast agents, when calculating payment rates for the associated nuclear medicine procedures or imaging procedures, respectively.

Response: In order to ensure that we capture appropriate diagnostic radiopharmaceutical costs for future ratesetting purposes once we began packaging payment for all of these products in CY 2008, we implemented nuclear medicine procedure-to-radiolabeled product claims processing edits in the I/OCE, effective January 2008, that required a diagnostic radiopharmaceutical to be present on the same claim as a nuclear medicine procedure for payment under the OPPS to be made. These edits ensure that hospitals submit correctly coded claims that report the HCPCS codes for the products and their charges that are necessary for performance of nuclear medicine procedures. We understand that the implementation of I/OCE claims processing edits may be challenging for a short period of time while hospitals become familiar with them, and while the edits are revised based on stakeholder feedback. However, we note that we implemented nuclear medicine procedure-to-radiolabeled product edits at the request of stakeholders based on concerns that hospitals were not always including a diagnostic radiopharmaceutical and its charge on the claim when a nuclear medicine procedure was provided. Stakeholders voiced complaints that these omissions led to inaccurate claims data for diagnostic radiopharmaceuticals and, once the OPPS began packaging payment for all diagnostic radiopharmaceuticals in CY 2008, there was inadequate payment for nuclear medicine procedures. We believe that the majority of hospitals are now able to submit claims that are able to pass these I/OCE edits, and that we have made the adjustments required to maintain the integrity of the edits while working with hospitals on special exceptions when a diagnostic radiopharmaceutical may not be provided with a nuclear medicine study. We discuss the nuclear medicine procedure-to-radiolabeled product edits and the evolution of our edit policy in greater detail in section II.A.2.d.(5) of this final rule with comment period. We implemented these edits because we believe that it is important to make sure that, when hospitals provide a packaged diagnostic radiopharmaceutical, the costs associated with the diagnostic

radiopharmaceutical are appropriately included on the same claim as the corresponding procedure to ensure that future ratesetting includes both the diagnostic radiopharmaceutical and the associated nuclear medicine procedure. These edits are especially important as payment for all diagnostic radiopharmaceuticals are packaged into the payment for the associated nuclear medicine procedure. The edits help ensure that hospitals are paid appropriately for diagnostic radiopharmaceutical costs, thus helping to maintain adequate patient access to nuclear medicine procedures.

We understand that some commenters believe that contrast agents may benefit from a similar set of I/OCE edits, and we are specifically requesting public comments on this topic in the final rule with comment period. Given that many contrast agents are low cost products with limited pharmacy handling costs and that advanced imaging studies are very common HOPD services, we are concerned that requiring the reporting of a contrast agent HCPCS code on every claim for an imaging study that specifies ''with contrast'' in its code descriptor could be quite administratively burdensome for hospitals. We are interested in the public's opinions on whether the potential benefits in capturing contrast agent costs that could occur as a result of a requirement for specific reporting of contrast agents on claims accompanied by claims processing edits to return incorrectly coded claims to hospitals for correction would outweigh the potential hospital burden of reporting these products and adjusting to a new set of claims processing edits.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to continue to package payment for all nonpass-through diagnostic radiopharmaceuticals and contrast agents, regardless of their per day costs. In doing so, we are accepting the APC Panel's recommendation to package payment for diagnostic radiopharmaceuticals for CY 2009. Given the inherent function of contrast agents and diagnostic radiopharmaceuticals as ancillary and supportive to the performance of an independent procedure, we continue to view the packaging of payment for contrast agents and diagnostic radiopharmaceuticals as a logical expansion of packaging for SCODs. In addition, as we initially established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66768), we are finalizing our proposal to continue to identify diagnostic radiopharmaceuticals specifically as those Level II HCPCS codes that include the term ''diagnostic'' along with a radiopharmaceutical in their long code descriptors, and therapeutic radiopharmaceuticals as those Level II HCPCS codes that include the term ''therapeutic'' along with a radiopharmaceutical in their long code descriptors.

During its March 2008 meeting, the APC Panel also recommended that CMS present data at the first CY 2009 APC Panel meeting on usage and frequency, geographic distribution, and size and type of hospitals performing nuclear medicine studies using radioisotopes in order to ensure that access is preserved for Medicare beneficiaries. We are accepting this recommendation and will present information to the APC Panel at its first CY 2009 meeting when initial claims data from CY 2008 will be available.

For more information on how we set CY 2009 payment rates for nuclear medicine procedures in which diagnostic radiopharmaceuticals are used and echocardiography services provided with and without contrast agents, we refer readers to sections II.A.2.d.(5) and (4), respectively, of this final rule with comment period.

3. Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs)

Section 1833(t)(14) of the Act, as added by section 621(a)(1) of Public Law 108–173, requires special classification of certain separately paid 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, as added by section 621(a)(1) of Public Law 108–173, 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.

In the CY 2006 OPPS proposed rule (70 FR 42728), we discussed the CY 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 reflected 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. 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 assigning drugs to the seven categories, MedPAC considered additional characteristics that contribute

to differential pharmacy handling costs, such as radioactivity, toxicity, mode of administration, and the need for special handling. While MedPAC was able to include information on a variety of drugs with many of these characteristics, hospitals participating in MedPAC's research were not able to provide sufficient cost information regarding the handling of outpatient radiopharmaceuticals for MedPAC to make a recommendation about overhead categories for these products.

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. We also proposed: (1) To combine several overhead categories recommended by MedPAC according to Table 24 of the proposed rule; (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 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. Both the MedPAC categories and the CY 2006 proposed categories are identified in Table 28 below.

TABLE 28—DRUG OVERHEAD CATEGORY GROUPINGS DISCUSSED IN THE CY 2006 OPPS PROPOSED RULE

MedPAC drug overhead category	Description	CMS proposed CY 2006 drug overhead category
Category 1	Orals (oral tablets, capsules, solutions)	Category 1.
Category 2	Injection/Sterile Preparation (draw up a drug for administration)	Category 2.
Category 3	Single IV Solution/Sterile Preparation (adding a drug or drugs to a sterile IV solution) or Controlled Substances.	Category 2.
Category 4	Compounded/Reconstituted IV Preparations (requiring calculations performed correctly and then compounded correctly).	Category 2.
Category 5	Specialty IV or Agents requiring special handling in order to preserve their therapeutic value or Cytotoxic Agents, oral (chemotherapeutic, teratogenic, or toxic) requiring personal protective equipment (PPE).	Category 3.
Category 6	Cytotoxic Agents (chemotherapeutic, teratogenic, or toxic) in all formulations except oral requiring PPE.	Category 3.
Category 7	Radiopharmaceutical: Basic and Complex Diagnostic Agents, PET Agents, Therapeutic Agents, and Radioimmunoconjugates.	

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. Therefore, we did not finalize this proposal for CY 2006.

As we noted in the CY 2006 OPPS final rule with comment period (70 FR 68640), findings from a MedPAC survey of hospital charging practices indicated that hospitals set charges for drugs, biologicals, and radiopharmaceuticals high enough to reflect their pharmacy handling costs as well as their acquisition costs. After considering all of the public comments received, in the CY 2006 OPPS final rule with comment period (70 FR 68642), we established a policy to provide a combined payment rate of ASP+6 percent for both the hospital's drug and biological acquisition costs and associated pharmacy overhead costs, as this was the equivalent average ASP-based amount to the aggregate cost from CY 2004 hospital claims data for separately payable drugs under the OPPS. We acknowledged the limitations of this methodology, namely that pharmacy overhead costs of specific drugs and biologicals are not directly related to their specific acquisition costs. We also solicited additional comments on future options for ways to identify and provide an alternative payment methodology for pharmacy overhead costs under the OPPS.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68091), we proposed and finalized a policy that provided 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 was higher than the equivalent average ASP-based amount calculated from claims of ASP+4 percent, but we adopted this methodology for stability while we continued to examine the issue of the costs of pharmacy overhead in the HOPD.

We continued to meet with interested pharmacy stakeholders regarding the various issues related to hospital charging practices and how these practices would affect our potential proposals for payment of drugs and pharmacy overhead under the OPPS. Many comments from the hospital industry reiterated that hospitals do not attach a specific pharmacy overhead charge to a particular drug. In particular, a more expensive drug with high pharmacy overhead costs does not commonly result in a sufficiently high hospital charge for the drug to account for all of the associated drug acquisition and pharmacy overhead costs. We have been told that hospitals frequently allocate a relatively greater pharmacy overhead charge to the single hospital charge for less expensive drugs to counterbalance the lesser charge for pharmacy overhead for more expensive drugs with high pharmacy overhead costs.

Therefore, the pharmacy overhead costs of one drug may be distributed among charges for many drugs. This practice of unequally distributing pharmacy overhead charges among all drugs provided by the hospital pharmacy makes the single CCR for cost center 5600 (Drugs Charged to Patients) applied for OPPS cost estimation of drugs through the revenue code-to-cost center crosswalk result in less accurate costs for individual drugs. The result is that the charges and estimated costs for less expensive drugs shoulder a higher burden of pharmacy overhead costs as compared to the charges and estimated costs for more expensive drugs.

Commenters have suggested that our OPPS methodology of applying a single CCR for the cost estimation of all drugs unfairly reduces payment amounts for separately payable expensive drugs, as the actual CCR varies widely across drugs. The concerns surrounding the impact on payment accuracy of differential hospital charging practices for pharmacy overhead costs resemble the concerns regarding charge compression that have been raised for expensive implantable devices over the past several years of the OPPS (72 FR 66599 through 66602). In general, differential hospital markup policies related to the cost of an item lead to overestimating the cost of inexpensive items and underestimating the cost of expensive items when a single CCR is applied to charges on claims.

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 paid 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. We believed that this methodology of reporting pharmacy overhead costs on an uncoded revenue center line would increase the accuracy of pharmacy overhead payments for drugs and biologicals as it would package the overhead cost for similar drugs into the commonly associated separately payable services, for example, by packaging the pharmacy overhead cost for a chemotherapy drug with the cost of the chemotherapy drug administration service also included on the claim.

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). While MedPAC supported the proposal for improving the accuracy of drug payment by incorporating variability in pharmacy overhead costs, most other commenters cited the increased hospital burden that would be associated with manipulating accounting systems and making manual calculations, along with concerns about making these changes to their billing operations while continuing to set charges for particular services that were the same for all payers. After hearing concerns about the burden of establishing a unique pharmacy overhead charge for every drug, 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 these concerns, 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, 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.

b. Payment Policy for CY 2009

The provision in section 1833(t)(14)(A)(iii) of the Act, as described above, continues to be applicable to determining payments for SCODs for CY 2009. This provision requires that, in CY 2009, 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, 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. In addition, section 1833(t)(14)(E)(ii) authorizes the Secretary to adjust APC weights for SCODs to take into account the MedPAC report relating to overhead and related expenses, such as pharmacy services and handling costs.

During this past year, we have met with a variety of stakeholders regarding different proposals for collecting pharmacy overhead cost information for setting OPPS payment rates. One such proposal was endorsed by several stakeholders during the March 2008 APC Panel meeting. Presenters to the APC Panel explained that CMS' methodology of using a single CCR to determine the acquisition and pharmacy overhead cost for all drugs attributes a greater relative share of pharmacy overhead cost to the lower-priced packaged drugs and a lower relative share of pharmacy overhead cost to the more expensive, separately payable drugs. Because the OPPS packages payment for drugs and biologicals with an estimated per day cost of $60 or less and estimates the equivalent average ASP-based amount based only on the costs of separately payable drugs, some pharmacy overhead cost that should be associated with separately payable drugs is being packaged into payment for the procedures that are performed with lower cost packaged drugs.

This stakeholder proposal suggested that CMS recalculate the equivalent average ASP-based amount based on the costs of packaged and separately payable drugs with HCPCS codes, rather than on our current methodology of calculating an ASP-based amount solely from claims data for separately payable drugs. CMS would then use this equivalent average ASP-based amount (or the physician's office payment rate of ASP+6 percent) to represent the acquisition and pharmacy overhead cost of all packaged drugs and would substitute this figure for the costs of packaged drugs in ratesetting for their associated procedures. The pool of money under the budget neutral OPPS that would result from this methodology that would package lower drug costs with associated procedures than our current methodology could then be distributed to OPPS payment in a number of ways, such as increasing the combined acquisition and overhead cost payment for separately payable drugs to a higher average ASP-based amount and/or providing separate payment for pharmacy overhead costs for either all drugs or only separately payable drugs based on a flat add-on rate or on tiers of pharmacy service complexity. The stakeholders presented APC median cost estimates demonstrating that their recommendation would significantly impact drug payment rates but would only change the majority of APC median costs by less than 2 percent.

At its March 2008 meeting, the APC Panel recommended that CMS work with stakeholders to further develop

recommendations on the validity of this methodology and conduct an impact analysis, with consideration for CY 2009 rulemaking. During the August 2008 meeting, the APC Panel recommended that CMS continue to look at refining the methodology for payment of pharmacy overhead and handling costs, and that CMS work with stakeholders to find a feasible approach for payment of drugs and pharmacy overhead. Further, the APC Panel recommended that CMS package the cost of all drugs that are not separately paid at ASP+5 percent, use the difference between these costs and CMS' costs derived from charges to create a pool that funds payment for pharmacy overhead services and pay hospitals for pharmacy service costs using this pool by making payments based on some system of categorization determined by CMS. In addition, the APC Panel recommended that CMS take into consideration the impact on beneficiaries' copayments.

Because CMS would redistribute pharmacy overhead cost when modeling payment rates for ratesetting, we concluded for the proposed rule that the suggested methodology would be administratively simple for hospitals. We stated our belief that that this approach also would refine the existing OPPS methodology for estimating pharmacy overhead cost in a budget neutral manner, without redistributing money from the payment for nondrug components of other services to payment for drugs. However, in the proposed rule, we also expressed our belief that substituting an average ASP-based amount (or the physician's office payment rate of ASP+6 percent) on claims for purposes of packaging drug costs into associated procedures would be a highly significant change to our established methodology. It is our longstanding policy to accept hospital charge data as it is reported on claims, in order to capture variability in hospitals' unique charges that is specific to each hospital's charging structure, as well as other potential efficiencies. The stakeholder recommendation would eliminate the expected variability in hospitals' costs for drugs that are packaged into their associated procedures.

In the CY 2009 OPPS/ASC proposed rule, we did not propose to adopt this stakeholder methodology. We noted our appreciation of this thoughtful approach to OPPS payment for pharmacy overhead costs, but we sought public comment on several issues that needed to be seriously considered before we could potentially propose the adoption of such a methodology, including, but not limited to, its implications for how we would more generally estimate the costs of items packaged into an independent service. In addition to our packaging of relatively inexpensive drugs that are integral to separately payable independent services, we package payment under the OPPS for the costs of a variety of other items and services. In addition, it was not clear to us what approach for redistributing pharmacy overhead dollars would be most accurate and operationally feasible for CMS. Therefore, in the CY 2009 OPPS/ASC proposed rule, we specifically invited public comment on this potential approach for estimating pharmacy overhead costs and redistributing pharmacy overhead payment under the OPPS.

Comment: Several commenters were not supportive of the stakeholder approach to payment for pharmacy overhead costs. The commenters were concerned about the potential redistributive effects of the proposal and the impact on beneficiaries of higher copayments for separately payable drugs.

However, the majority of commenters expressed support for the stakeholder recommendation to redistribute a portion of pharmacy overhead costs from payment for packaged drugs and biologicals through payment for the associated procedures to payment for separately payable drugs and biologicals in a budget neutral manner. In general, the commenters believed that CMS' concerns regarding the substitution of ASP information on hospital claims to replace the costs reported by hospitals would have no other implications for OPPS cost estimation because no other item or service has a similar market-based payment methodology (such as ASP) for identifying hospital costs. The commenters noted that CMS already uses a non-standard methodology in providing payment for drugs and biologicals based on the ASP methodology. The commenters viewed the stakeholder proposal as a more accurate application of the standard CMS methodology. In addition, the commenters believed that adoption of the stakeholder approach to redistribute pharmacy overhead costs more accurately to separately payable drugs would be necessary if CMS were to continue to package payment for some drugs and biologicals with per day costs at or below the proposed CY 2009 drug packaging threshold.

Further, many commenters stated that the stakeholder recommendation for payment of drugs and pharmacy overhead costs would be administratively simple for hospitals to implement and would provide a more accurate payment solution for separately payable drugs and biologicals. Some commenters believed that implementing this approach could be relatively straightforward for CMS, and could include a processing step in the I/OCE that would add on the appropriate standard pharmacy overhead payment whenever a drug HCPCS code was billed.

Finally, many commenters also supported the redistribution of the resulting pharmacy overhead payments through three payment levels based on the estimated pharmacy overhead resource costs specific to each drug HCPCS code. The commenters included suggestions for drug assignments to three tiers of pharmacy overhead categories and suggested that these additional payments could be programmed into the I/OCE so that they would require no additional administrative changes by hospitals.

Many commenters concluded that the recommended stakeholder approach had been sufficiently reviewed by both hospital stakeholders and CMS, and they urged CMS to adopt this payment methodology for CY 2009.

Response: As we stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41489 through 41490), we appreciate the creative approach to OPPS payment for pharmacy overhead costs as described above. We have continued to review and discuss this stakeholder recommendation in meetings with interested stakeholders and during the August 2008 APC Panel meeting. We remain interested in further exploring this approach that certain stakeholders have developed as a solution to the issue of uneven distribution of OPPS payment for pharmacy overhead costs, and we believe that such an approach, or modifications of the recommended approach, could potentially provide more accurate OPPS payment for drugs and biologicals in the future.

However, we do not believe that it would be appropriate to adopt such a payment approach for CY 2009 that is so different from our proposal for several reasons. First, as we noted in the CY 2006 OPPS final rule with comment period (70 FR 68640), findings from a MedPAC survey of hospital charging practices indicated that hospitals set charges for drugs, biologicals, and radiopharmaceuticals high enough to reflect their pharmacy handling costs as well as their acquisition costs. Similarly, in the Medicare Claims Processing Manual (Pub. 100–04, Chapter 17, Section 90.2), we have instructed hospitals to include both acquisition costs and pharmacy overhead or nuclear medicine handling

costs in their line-item charges for drugs, biologicals, and radiopharmaceuticals. Beyond drugs and biologicals, we expect that hospitals consider costs when setting charges for all hospital services. We believe that hospitals have internal policies for setting charges and are internally consistent when setting charges, although the manner in which charges are set relative to cost likely varies by hospital. Application of a hospital-specific CCR to estimate costs for purposes of OPPS ratesetting creates cost estimates that are internally consistent with the hospital's charging structure and retain the variability in charges, and variability in cost by association, experienced by each hospital. We observe a wide range in our estimates of costs for various drugs and biologicals, suggesting that hospitals have different estimated costs for these items. In part, our longstanding policy to accept hospital charge data as they are reported by hospitals is an attempt to appropriately capture the variability in hospitals' unique charges that reflects real differences in cost and other efficiencies at each hospital. Further, for all services, external estimates of cost created outside the hospital's billing and accounting information would not be based on the relative estimated costs for the hospital. We also utilize hospital charge data as reported by hospitals to avoid inappropriately redistributing money based on external estimates of costs from widely different sources. The stakeholder recommendation would eliminate the expected variability in hospitals' costs for drugs that are packaged into their associated procedures and substitute a static, external estimate of cost for one that would otherwise be established by the hospital's internal billing and accounting structure. While certain stakeholders have demonstrated how this approach would impact the median costs for drug administration services, the concept of substituting external cost estimates for certain items or services in the context of an otherwise internally consistent relative cost structure has importance for packaging costs in other APCs.

Second, because we have not yet fully analyzed a comprehensive drug payment methodology that would follow this general approach, nor have we provided sufficient information on the impacts of this proposal to the public, we do not believe that adopting this approach for CY 2009 would be appropriate. Therefore, we are not accepting the APC Panel's August 2008 recommendation to redistribute the pharmacy overhead costs currently associated with packaged drugs to a pool that would pay for pharmacy services, and pay for these pharmacy services by making payments based on a system of drug categorization established by CMS. As we did not propose a methodology like the stakeholder's model or the APC Panel's recommended approach, or a variation of that model, for the CY 2009 OPPS, we have not assessed the impact such a change would have on payment for other OPPS services, including those services with significant packaged drug costs, on payment to different classes of hospitals, or on beneficiary copayments. However, we are particularly interested in further exploring this approach, especially in light of the overwhelming lack of public support for our proposal to split the 5600 (Drugs Charged to Patients) cost center on the Medicare cost report into two new cost centers, Drugs With High Overhead Cost Charged To Patients and Drugs With Low Overhead Cost Charged To Patients, as discussed in more detail below.

As we explained in the CY 2009 OPPS/ASC proposed rule, recently RTI completed its evaluation of the OPPS cost-based weight methodology in general, and charge compression in particular. Pharmacy stakeholders have already noted that accurately estimating pharmacy overhead cost is intimately related to the CCR used to estimate costs from claims' charges. As discussed above, hospitals have informed us that they redistribute the cost of pharmacy overhead from expensive to inexpensive drugs when setting charges for drugs.

RTI determined that hospitals billing a greater percent of drug charges under revenue code 0636 (Drugs requiring detail coding) out of all revenue codes related to drugs had a significantly higher CCR for cost center 5600 (Drugs Charged to Patients). ''These findings are consistent with the a priori expectation that providers tend to use lower markup rates on these relatively expensive items, as compared with other items in their CCR group.'' (RTI report, ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights,'' July 2008). RTI, in its March 2007 report, noted that hospitals billing a greater percent of drug charges under revenue code 0258 (IV solutions) out of all revenue codes related to drugs had a significantly lower CCR for cost center 5600. In the short term, RTI recommended that CMS adopt regression-adjusted CCRs under the OPPS for drugs requiring detail coding (reported under revenue code 0636) and for IV solutions (reported under revenue code 0258) for purposes of estimating median costs. To eliminate the need for simulated CCRs in the longer term, RTI recommended that CMS create a new standard cost center in the cost report for drugs requiring detail coding (reported under revenue code 0636) to mitigate charge compression by acquiring more specific CCRs (RTI report, ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights,'' July 2008).

As discussed further in section II.A.1.c. of this CY 2009 OPPS/ASC final rule with comment period and consistent with our proposal for the FY 2009 IPPS, we did not propose to adopt regression-based CCRs for cost estimation in any area of the CY 2009 OPPS, including drugs requiring detail coding and IV solutions. Instead, we stated that we believed that RTI's empirical findings would appropriately be addressed through concrete steps to improve the quality of accounting information used to estimate future costs from drug charges. Cognizant of public comments on past proposals, we also stated that we believed that this should be done in a manner that is fairly simple for hospitals to implement.

For CY 2009, we proposed to continue our policy of making a combined payment for the acquisition and pharmacy overhead costs of separately payable drugs and biologicals at an equivalent average ASP-based amount calculated based on our standard methodology of estimating drug costs from claims. Using updated data, for the CY 2009 proposed rule, after determining the proposed CY 2009 packaging status of drugs and biologicals, we estimated the aggregate cost of all drugs and biologicals (excluding therapeutic radiopharmaceuticals for which no ASP data were available) that would be separately payable in CY 2009 based on costs from hospital claims data and calculated the equivalent average ASP-based payment rate that would equate to the aggregate reported hospital cost. The results of our analysis indicated that setting the payment rates for drugs and biologicals that would be separately payable in CY 2009 based on hospital costs would be equivalent to providing payment, on average, at ASP+4 percent. Therefore, we proposed to pay for separately payable drugs and biologicals under the CY 2009 OPPS at ASP+4 percent because we believed that this was the best currently available proxy for average hospital acquisition cost and associated pharmacy overhead costs.

Comment: Several commenters cited methodological concerns about the approach CMS used to calculate the equivalent average ASP-based payment amount for separately payable drugs and biologicals.

Some commenters noted that the statute requires drug cost surveys for payment purposes for SCODs under the OPPS, and the most recent survey available is outdated as it was performed in CY 2004 by the GAO. The commenters stated that the statute specifically required survey data as the basis for hospital acquisition costs in order to provide a more appropriate payment methodology for drugs and biologicals, instead of costs from claims data. They concluded that, by not performing a survey and by not paying for drugs and biologicals at the physician's office rate, CMS was not in compliance with the statute. The commenters acknowledged that drug cost surveys are difficult to perform. However, they believed that either a survey should be performed or payment should be made at ASP+6 percent, in accordance with the requirement of the statute.

Commenters reiterated that hospitals disproportionably mark up their charges for low cost drugs and biologicals to account for pharmacy overhead costs. They indicated that while the aggregate charges for inexpensive and expensive drugs may include the total pharmacy overhead costs of the hospital, the charges for individual drugs and biologicals do not represent the specific acquisition and pharmacy overhead costs of that particular drug or biological. The commenters explained that hospitals apply proportionately smaller markups to higher cost items and proportionately larger markups to lower cost items. The commenters believed that when CMS applies a single CCR to adjust charges to costs for these drugs and biologicals, charge compression leads to misallocation of the pharmacy overhead costs associated with high and low cost drugs and biologicals during ratesetting.

Commenters noted that by using only separately payable drugs in the calculation of the equivalent average ASP-based amount, the pharmacy overhead costs associated with these separately payable drugs that are disproportionately included in the charges for packaged drugs are not factored into the calculation, resulting in an artificially low ASP add-on percentage. The commenters suggested using the costs of both packaged drugs and separately payable drugs when calculating the equivalent average ASP-based payment amount for separately payable drugs, as they argued that this would provide a more accurate ASP percentage payment for separately payable drugs. As an alternative, the commenters recommended that CMS could eliminate the drug packaging threshold and provide separate payment for all Part B drugs under the OPPS.

Finally, the commenters noted that CMS included, in the calculation of the costs of separately payable drugs and biologicals, OPPS claims from hospitals that receive Federal discounts on drug prices under the 340B program. The commenters pointed out that hospital participation in the 340B program had grown substantially over the past few years, and they believed that the costs from these hospitals now constituted a significant proportion of hospital drug costs on CY 2007 OPPS claims. The commenters stated that including 340B hospital claims data when comparing aggregate hospital costs based on claims data to ASP rates contributed to an artificially low equivalent average ASP-based payment rate because ASP data specifically exclude drugs sales under the 340B program.

Response: As discussed above, the provision in section 1833(t)(14)(A)(iii) of the Act continues to be applicable to determining payments for SCODs for CY 2009. 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 or if hospital acquisition cost data are not available, then the average price for the drug in the year established under section 1842(o), 1847A, or 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of section 1833(t)(14)(iii)(II) of the Act. In the CY 2006 OPPS final rule, we compared hospital drug cost data that were available to us at the time, specifically: (1) Data from the GAO survey; (2) hospital claims data from CY 2004; and (3) ASP information. In addition, we discussed our methodology for comparing these data that represented different timeframes from 2004 to 2006. As a result of our analysis comparing these three sources, we concluded that, on average, the costs from hospital claims data representing SCODs were roughly equivalent to payment ASP+6 percent. Therefore, we finalized a policy that used our hospital claims data as a proxy for average hospital acquisition cost and provided payment for separately payable drugs that do not have pass-through status at ASP+6 percent in CY 2006 (70 FR 68639 through 68642). The commenters are correct that the statute allows for the use of the methodology described in section 1842(o), section 1847A or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary, but this is only when hospital acquisition cost data are not available. We believe that we have established our hospital claims data as an appropriate proxy for average hospital acquisition costs, taking the GAO survey information into account for the base year. While we have not yet performed hospital drug acquisition cost surveys similar to the GAO survey, we note that the statute only calls for ''periodic'' surveys, and we are considering the possibility of such a survey at some point in the future.

In addition, we understand that because hospital charges for drugs are adjusted to cost by a single CCR, but hospitals continue to apply differential markups to their charges for low and high cost drugs and biologicals, the result is an overestimation of costs for less expensive drugs and an underestimation of costs for more expensive drugs. In order to more accurately identify costs for drugs, we proposed to split the current single drug cost center into two standard cost centers on the Medicare cost report. By creating two standard cost centers (one for Drugs With High Overhead Cost Charged to Patients, the other for Drugs With Low Overhead Cost Charged to Patients), we believed that the resulting CCRs would provide a more accurate ASP-based estimate for those drugs that are separately paid, as each individual drug charge would be subject to a more accurate CCR, depending on whether the drug was classified by the hospital as having high or low overhead costs. We discuss this proposal, the public comments we received, and our final policy in detail below.

It has been our policy, since CY 2006, to only use separately payable drugs in the calculation of the equivalent average ASP-based payment amount under the OPPS. We do not include packaged drugs and biologicals in this analysis because cost data for these items are already accounted for within the APC ratesetting process through the median cost calculation methodology discussed in section II.A.2. of this final rule with comment period. To include the costs of packaged drugs in both our APC ratesetting process (for associated procedures present on the same claim) and in our ratesetting process to establish an equivalent average ASP-based payment amount for separately payable drugs and biologicals would give these data disproportionate

emphasis in the OPPS system by skewing our analyses, as the costs of these packaged items would be, in effect, counted twice. Accordingly, we are not adopting the suggestion from commenters that we include all packaged and separately payable drugs and biologicals when establishing an equivalent average ASP-based rate to provide payment for the hospital acquisition and pharmacy handling costs of drugs and biologicals. However, we remind commenters that because the costs of packaged drugs, including their pharmacy overhead costs, are packaged into the payments for the procedures in which they are administered, the OPPS provides payment for both the drugs and the associated pharmacy overhead costs through the applicable procedural APC payments.

We also are not adopting the alternative recommendation by some commenters that we eliminate the drug packaging threshold and pay separately for all drugs and biologicals with HCPCS codes. As we have stated previously (71 FR 68085), we believe that it is appropriate, at a minimum, to continue a modest drug packaging threshold under the OPPS. Packaging is a fundamental component of a prospective payment system that contributes to important flexibility and efficiency in the delivery of high quality outpatient care.

We have had several meetings with interested stakeholders over the past year regarding the drug costs of hospitals that participate in the Federal 340B program, and we are interested in gathering more information on their potential influence on our methodology for calculating payment rates for separately payable drugs. Specifically, we are requesting comments on this final rule with comment period that address: (1) Whether all HOPDs from a participating provider furnish drugs purchased under the 340B pricing program or only a subset of departments; (2) whether all drugs are available to participating hospitals under the 340B program; (3) whether hospital drugs provided to inpatients are purchased by hospitals at 340B program prices if the hospital is a participating provider; (4) what proportion of a participating hospital's total costs and charges for drugs reflect drugs purchased through the 340B program; (5) whether hospitals participating in the 340B program receive other manufacturer discounts that impact their final drug cost; (6) whether hospitals set different charges for drugs purchased through the 340B program than their charges for those same drugs purchased outside the program; (7) the impact 340B drug purchasing agreements have on OPPS hospital claims data used to estimate drug costs; (8) whether hospitals participating in the 340B program should be paid for drugs under the OPPS at adjusted rates because they have different average hospital acquisition costs for drugs and biologicals from nonparticipating hospitals, (9) whether we should use the equitable adjustment authority in section 1833(t)(2)(E) of the Act to adjust OPPS payments to hospitals for separately payable drugs based on hospitals' participation in the 340B program, so that drug payment for the two classes of hospitals (340B participating and 340B nonparticipating) would reflect the averge drug acquisition and pharmacy overhead costs specific to each class of hospital; and (10) any additional information that would assist us in understanding and considering this issue for potential rulemaking in the future.

As discussed above, in the CY 2009 OPPS/ASC proposed rule, we included a proposal to break the single standard cost center 5600 into two standard cost centers, Drugs with High Overhead Cost Charged to Patients and Drugs with Low Overhead Cost Charged to Patients, to reduce the reallocation of pharmacy overhead cost from expensive to inexpensive drugs and biologicals when setting an equivalent average ASP-based payment amount in the future. This proposal is consistent with RTI's recommendation for creating a new cost center whose CCR would be used to adjust charges to costs for drugs requiring detail coding. However, we noted that while improved CCRs would more accurately estimate the ASP-based amount for combined drug and pharmacy overhead payment, they would not capture within HCPCS code variability in pharmacy handling costs resulting from different methods of drug preparation used by hospitals. As discussed above, we believe that improved and more precise cost reporting is the best way to improve the accuracy of all cost-based payment weights, including relative weights for the IPPS MS–DRGs. Because both the IPPS and the OPPS rely on cost-based weights derived, in part, from data on the Medicare hospital cost report form, we indicated that public comment on the proposed change to the cost report to break the single standard cost center 5600 into two standard cost centers should address any impact on both the inpatient and outpatient payment systems.

We stated in the proposed rule that this proposal would not affect OPPS cost estimation for radiopharmaceuticals for several reasons. First, we would not expect the costs and charges for radiopharmaceuticals to be assigned to cost center 5600. Rather, cost center 4300 (Radioisotope) is more appropriate for these items. Second, our claims data demonstrated that some hospitals continued to bill radiopharmaceuticals under revenue code 0636, contrary to UB–04 instructions (Official UB04 Data Specifications Manual, AHA 2007, p. 127), specifically noting that radiopharmaceuticals should be billed under revenue codes 0343 (Diagnostic Radiopharmaceuticals) and 0344 (Therapeutic Radiopharmaceuticals). We believed that billing radiopharmaceuticals under revenue code 0636 could be a result of dated CMS' guidance regarding billing radiopharmaceuticals under revenue code 0636. On April 8, 2008, we deleted this guidance from our Claims Processing Manual through administrative issuance (Transmittal 1487, Change Request 5999). Finally, RTI did not observe evidence of differential markup in cost center 4300 (for hospitals reporting the cost center) for products reported under revenue codes 0343 and 0344 (RTI report, ''Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights,'' July 2008).

In the CY 2009 OPPS/ASC proposed rule, we discussed several ways we could define the new cost centers for purposes of hospital reporting. First, we could adopt the assumptions behind RTI's empirical findings and require that hospitals simply report the costs and charges associated with revenue code 0636 in the proposed new cost center Drugs with High Overhead Cost Charged to Patients. This approach would require hospitals to report charges and costs for all other drugs in the proposed new cost center Drugs with Low Overhead Cost Charged to Patients. We believed this approach would be administratively simple for hospitals to implement because it would easily align revenue code and cost center relationships and would not require hospitals to otherwise categorize drugs or estimate a unique pharmacy overhead cost for each drug. Notwithstanding our requirement for hospitals to report, consistent with CPT and CMS instructions, all services described by HCPCS codes provided in an encounter, to the extent that hospitals reported HCPCS codes for drugs that are not packaged, this

approach might isolate costs and charges for drugs that are separately paid under the OPPS for purposes of more accurately estimating their costs. While we believed that RTI's findings suggested an increase in the CCR for adjustment of drug charges to costs would result from isolating the costs and charges for drugs billed under revenue code 0636, one limitation of this approach is that it would not fully mitigate the disproportionate allocation of pharmacy overhead cost reflected in differential markup. Although clearly an improvement in accuracy over current cost estimation, it is likely that significant variability in markup and overhead cost for drugs currently billed under revenue code 0636 would remain in the new cost center CCR for Drugs with High Overhead Cost Charged to Patients.

Second, we could set a cost threshold for drug acquisition and pharmacy overhead cost for purposes of including costs and charges for the drug in one of the two proposed new cost centers. If we were to implement this methodology, we potentially could set the threshold at the OPPS drug packaging threshold, which was proposed to be $60 for CY 2009. This would clearly identify those drugs that would be billed in each cost center because all drug and biological HCPCS codes would be assigned either separately payable or packaged status under the CY 2009 OPPS. However, we believed that using the OPPS drug packaging threshold could be too low, and probably would not identify a cost point that would maximize cost differences between drugs with relatively high pharmacy overhead cost and drugs with relatively low pharmacy overhead cost. This approach has the benefit of considering cost, which appears largely to determine the amount of markup for pharmacy overhead costs a hospital incorporates into drug charges. Although some high cost drugs may have low pharmacy overhead costs, in general this alternative might do a better job of improving cost estimates for drugs with high pharmacy overhead costs through the use of more specific CCRs than the first alternative discussed, a cost center that would include all drugs currently billed under revenue code 0636. On the other hand, we were uncertain as to how we would identify the most appropriate cost threshold amount, or the manner and frequency with which we would update the threshold. More importantly, we expressed concern that identifying the unique acquisition and overhead cost for each drug could impose a comparable administrative burden as other prior proposals.

Third, as we discussed in the proposed rule, we could also set a cost threshold for pharmacy overhead specifically to define high versus low overhead cost for purposes of reporting costs and charges for drugs in the two new cost centers. This alternative would require hospitals to identify the cost of pharmacy overhead for every drug in order to assign it to a cost center. This approach would most accurately isolate drugs with high and low overhead costs, respectively. Therefore, the resulting CCRs would better estimate the average acquisition and overhead cost for these drugs. On the other hand, as with the second alternative, we were uncertain as to how we would identify the most appropriate pharmacy cost threshold amount, or the manner and frequency with which we would update the threshold. Further, this approach could also impose a significant hospital administrative burden, comparable to the burden identified by commenters regarding other prior proposals.

A fourth approach discussed in the proposed rule would be to instruct hospitals to assign those drugs they administer in the OPPS to the two proposed new cost centers according to the categories discussed in the CY 2006 final rule with comment period and presented in Table 24 of the CY 2009 OPPS/ASC proposed rule. Under this methodology, drugs falling in CMS categories 1 and 2 would be billed under revenue codes 025X or 063X (other than 0636) and captured in the cost report in the proposed new cost center Drugs with Low Overhead Cost Charged to Patients, while drugs falling in CMS category 3 would be billed under revenue code 0636 and reported in the proposed new cost center Drugs with High Overhead Cost Charged to Patients. CMS would provide some examples in the cost report instructions of appropriate drugs for each category. We indicated that we were aware that some pharmacy stakeholders have already categorized drug and biological HCPCS codes into the three CMS pharmacy overhead categories that were proposed for CY 2006. Because pharmacy overhead costs may vary depending on the preparation of a specific product at an individual hospital and hospital accounting also varies, the same drug could appear in a different cost center across hospitals. However, we indicated that we did not believe it would be necessary for hospitals to assign exactly the same drugs to each of the two proposed new cost centers, as long as hospitals' assessment of the pharmacy overhead cost category is consistent with their billing of these drugs under revenue codes 063X (other than 0636) and 025X or 0636 and the inclusion of these drugs in the associated cost centers. Prospectively, the OPPS cost estimation methodology would use the CCR calculated for the proposed new cost center Drugs with High Overhead Cost Charged to Patients to adjust drug charges billed under revenue code 0636 to cost and the CCR calculated for the proposed new cost center Drugs with Low Overhead Cost Charged to Patients to adjust drug charges billed under revenue codes 025X and 063X (other than 0636) to cost for determining drug acquisition and pharmacy overhead costs. We indicated in the proposed rule that we believed this fourth approach would best estimate a CCR for drugs with high pharmacy overhead cost and relatively low markup as reflected in hospitals' charges. Because the number of drugs in pharmacy overhead category three would be limited based on the specific category description, this approach should more accurately address the limited markup for very expensive drugs with high pharmacy overhead costs, where charges do not reflect the hospitals' pharmacy overhead costs for those drugs. We also believed that hospitals would find this alternative easier to implement than any policy requiring hospitals to identify a unique total acquisition and overhead cost or a specific pharmacy overhead cost for each drug for purposes of assigning the drug's costs and charges to one of the two proposed new cost centers. However, we realized that there would still be some additional administrative burden for hospitals that had not yet determined the appropriate pharmacy overhead category for each of their drugs, and that they would need to educate their billing staff, to modify their chargemasters, and to adapt other billing software.

In summary, we proposed to pay for the combined average acquisition and pharmacy overhead cost of separately payable drugs and biologicals at ASP+4 percent based on the costs of separately payable drugs calculated from claims data under the CY 2009 OPPS. In addition, we proposed to create two new cost centers when we revise the Medicare hospital cost report form, specifically Drugs with High Overhead Cost Charged to Patients and Drugs with Low Overhead Cost Charged to Patients. We indicated that we expected that CCRs from these 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 pharmacy overhead costs. In the proposed rule, we specifically invited public comment on the policy and operational benefits, challenges, and concerns that might be associated with these proposals, specifically as they related to our proposed approach to distinguishing between drugs and biologicals for purposes of inclusion in the two proposed new cost centers and the other alternatives discussed above.

During its August 2008 meeting, the APC Panel recommended that CMS not implement the proposed change to the cost center for drugs on the Medicare cost report. In addition, the Panel recommended that CMS continue to provide payment for drugs at a rate of no less than ASP+5 percent. We discuss our response to these recommendations along with our responses to public comments below.

Comment: A few commenters supported CMS' proposal to split the single standard cost center for drugs (5600—Drugs Charged to Patients) into two standard cost centers (Drugs With High Overhead Cost Charged to Patients and Drugs With Low Overhead Cost Charged to Patients). Several of these commenters, including MedPAC, recommended splitting the single 5600 cost center into several cost centers, not just the two presented in the OPPS proposed rule. The commenters believed that this would create even more accurate CCRs for drug cost estimates that could be used for future ratesetting purposes.

However, the majority of commenters did not support this proposal. Commenters noted that, as in past proposals made by CMS to more specifically incorporate differential hospital charging practices for pharmacy overhead costs in ratesetting, this proposal was administratively burdensome for hospitals and was not likely to result in reliable information for future ratesetting purposes. The commenters pointed to the differences between the costs of drugs provided in the HOPD, which include significant personnel and specialized equipment costs that would need to be allocated between drugs assigned to the two proposed cost centers, and the costs of medical supplies, which principally include the costs of the items themselves. They cited these differences as the main reason many commenters opposed to the proposed drug cost center split in turn supported the policy finalized in the FY 2009 IPPS final rule (73 FR 48453) to split the current single cost center for Medical Supplies Charged to Patients into two cost centers, one for Medical Supplies Charged to Patients and another for Implantable Devices Charged to Patients, to account for charge compression in the payment weights for high cost medical devices under the IPPS and the OPPS. While this latter change was operationally feasible for hospitals, many commenters believed that the proposed changes to the cost center for drugs were either operationally impossible or would place a significant administrative burden on hospitals. In addition, the commenters noted substantial problems with each of options presented for classifying drugs into one of the two proposed cost centers. Finally, the commenters noted that the associated requirement to begin reporting HCPCS codes for inpatient drugs was not possible for many hospitals by January 1, 2009.

Some commenters also expressed frustration that this proposal because it was based in the hospital cost report, would take several years to impact OPPS payment rates for drugs. While only a few commenters requested that CMS implement immediate payment changes, such as the regression-based approach recommended by RTI, many other commenters specifically rejected RTI's recommendation to apply a regression-based approach to cost estimation for drugs and biologicals.

Response: Once again, we appreciate the commenters' many suggestions on ways to collect hospital pharmacy cost data and the commenters' concerns regarding our proposal. As noted by the overwhelming majority of commenters, we understand that our CY 2009 proposal to change the standard cost center for drugs could lead to increased hospital burden. Our intent in making this proposal was to address the issue of differential hospital markup policies for drugs that stakeholders believe result in inaccurate hospital payment and not to create hospital burden. We have made numerous attempts over the past several years to adopt methods for gathering hospital information regarding pharmacy overhead costs for possible use in future OPPS ratesetting. However, all of our prior proposals have resulted in feedback citing increased hospital burden and recommendations that we not adopt any of the proposals.

We remain interested in finding methodologies to further refine our payment methodology for drugs and biologicals under the OPPS. While we continue to believe that more refined and accurate hospital accounting data are the preferred long-term solution to mitigate charge compression in hospital cost-based weights, based on the public comments on this proposal and the recommendation of the APC Panel, we have decided not to finalize our proposal to split the 5600 cost center into two standard cost centers. We remain interested in continuing our dialogue with hospital stakeholders as we continue to explore reasonable ways to allocate pharmacy overhead costs to low and high cost drugs and as we further analyze the stakeholder proposal, discussed above.

Comment: Some commenters agreed with the APC Panel's recommendation to continue providing payment for separately payable drugs at no less than ASP+5 percent. However, the majority of commenters recommended that CMS provide payment for separately payable drugs and biologicals at ASP+6 percent for CY 2009. Some commenters noted that payment at ASP+6 percent would eliminate a site-of-service differential that would otherwise exist between the HOPD and physicians' office settings if HOPDs were paid at ASP+4 percent, as proposed, while physicians' offices were paid at ASP+6 percent in CY 2009.

In addition, some commenters expressed concern that hospitals may be unable to purchase many drugs at ASP+4 percent, and that this rate would be insufficient for certain drugs when considering both acquisition costs and pharmacy overhead costs. The commenters believed that the proposed payment rate could lead to access problems for Medicare beneficiaries.

Response: In analyzing updated claims data for the CY 2009 final rule with comment period, we again performed the analysis described in the CY 2009 proposed rule by comparing the aggregate costs for separately payable drugs and biologicals on claims to the ASP-based payment rates, weighting these HCPCS codes by their OPPS volumes, and calculating an equivalent average ASP-based payment rate for drugs and biologicals provided in HOPDs for CY 2009. We used updated CY 2007 mean unit costs and drug volumes and updated ASP data for this final rule analysis to determine the final packaging status for each drug. The result of our final analysis using updated hospital claims data for the full CY 2007 year and updated CCRs is that the equivalent average ASP-based payment amount for separately payable drugs and biologicals, including pharmacy handling costs, is equal to ASP+2 percent for CY 2009. Therefore, according to our CY 2009 proposal for payment of separately payable drugs and biologicals which includes pharmacy overhead payment, based on separately payable drug costs from CY 2007 hospital claims, the OPPS payment rate for separately payable drugs and biologicals would be ASP+2 percent.

We acknowledge that different payment rates for drugs and biologicals provided in the physician's office and HOPD settings are of concern to some commenters. However, the OPPS, the MPFS physician's office payments for services, and physician's office payments for Part B drugs are based on very different payment methodologies. In particular, the OPPS relies upon costs from the most updated claims and Medicare cost report data to develop payment rates. On the other hand, the MPFS pays for services based on estimates of input costs and pays for drugs and biologicals at ASP+6 percent, as required by statute. Therefore, it is not surprising to us that the estimated costs of drug and biologicals and their associated pharmacy overhead, like many other OPPS services, could be different in the HOPD than in the physician's office, resulting in different payments in the two settings. We do not believe that different payment rates for drugs and biologicals in HOPD or physicians' office settings would create beneficiary access problems for drug administration services because we have not seen problems with access in the two settings for other types of services, including diagnostic studies, surgical procedures, and visits, which generally have different payment rates under the two payment systems (unless there is an applicable externally applied statutory cap to payment, such as the cap on payment for imaging services provided in the physician's office based on the OPPS rates).

As we stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66763), after a period of continuing ASP+6 percent payment in CY 2007 while we gathered additional information regarding pharmacy overhead costs, we believe that it is most appropriate at this point to continue to pay for drugs and biologicals and their associated pharmacy overhead costs using an ASP-based system, but to determine the relative ASP percent based on hospital costs from claims rather than provide payment at ASP+6 percent that would be paid in the physician's office or at ASP+5 percent as recommended by the APC Panel for CY 2009. We note that, for CY 2008, we adopted a payment rate of ASP+5 percent as a transition between the CY 2007 OPPS payment rate of ASP+6 and the claims-based CY 2008 final rule rate of ASP+3 percent.

We continue to believe that pharmacy overhead and handling costs are included by hospitals in their drug charges and should be paid through the drug payment and that a payment rate reflecting costs from claims data is appropriate. However, we believe that a transition to a refined claims-based payment methodology continues to be appropriate as well, while we further explore the complex issues surrounding hospital allocation of pharmacy overhead costs to drug charges and differential hospital drug costs based on hospital participation in the 340B program. Therefore, we will provide a transitional payment rate of ASP+4 percent in CY 2009 for separately payable drugs and biologicals, the same payment rate that was proposed for CY 2009 based on hospital claims data available for the CY 2009 OPPS/ASC proposed rule. Moreover, we note that payment at ASP+4 percent is consistent with a 50/50 blend of the CY 2008 payment rate of ASP+5 percent and the final CY 2009 equivalent average ASP-based payment amount of ASP+2 percent, as caclculated from CY 2007 claims data available for this final rule with comment period. This is similar to our CY 2008 transition methodology for payment of separately payable drugs and biologicals. While payment at ASP+4 percent is slightly higher than the equivalent average ASP-based payment amount for all hospitals that we calculated from hospital costs according to the methodology we have used since CY 2006, we believe that another transitional payment year appropriately allows for a gradual change in hospital payment from the CY 2008 drug payment rate to a refined claims-based payment methodology. This CY 2009 transitional payment should help to ensure continued access to separately payable drugs and biologicals in the HOPD, while also providing us with another year to explore the complex issues surrounding hospital allocation of pharmacy overhead costs to drug charges and differential hospital drug costs based on hospital participation in the 340B program, in order to determine if a refined methodology could improve payment accuracy, while also ensuring equitable payments. In summary, we will provide another year of transitional payment for CY 2009 at ASP+4 percent for separately payable drugs and biologicals and associated pharmacy overhead costs. As a result, we are not accepting the recommendation of the APC Panel to continue to pay for separately payable drugs and biologicals at no less than ASP+5 percent for CY 2009.

As noted above, we will be further exploring the impact of hospitals participating in the 340B program on hospital drug costs calculated from OPPS claims during this CY 2009 transitional year, where the separately payable drug costs from OPPS claims would have otherwise led us to pay all hospitals at ASP+2 percent according to our proposed methodology. Given stakeholders' comments about increasing hospital participation in the 340B program and the significantly reduced drug acquisition costs that may result, we are considering various approaches to improve the accuracy of OPPS payment to all hospitals for the acquisition and pharmacy overhead costs of separately payable drugs, including whether we should use the equitable adjustment authority in section 1833(t)(2)(E) of the Act to adjust OPPS payments to hospitals for separtately payable drugs based on hospitals' participation in the 340B program, so that drug payment for the two classes of hospitals (340B participating and 340B nonparticipating) would reflect the average drug acquisition and pharmacy overhead costs specific to each class of hospital.

Comment: One commenter requested that CMS create an HCPCS J-code for tositumomab, currently provided under a radioimmunotherapy regimen and billed as part of HCPCS code G3001 (Administration and supply of tositumomab, 450 mg). The commenter argued that because tositumomab is listed in compendia, is approved by the FDA as part of the BEXXAR® regimen, and has its own National Drug Code (NDC) number, it should be recognized as a drug and, therefore, be paid as other drugs are paid under the OPPS methodology, instead of having a payment rate determined by hospital claims data. The commenter suggested that a payment rate could be established using the ASP methodology.

Response: We have consistently noted that unlabeled tositumomab is not approved as either a drug or a radiopharmaceutical, but it is a supply that is required as part of the radioimmunotherapy treatment regimen (November 27, 2007 OPPS/ASC final rule with comment period for CY 2008 (72 FR 66765); November 10, 2005 OPPS final rule with comment period for CY 2006 (70 FR 68654); November 7, 2003 OPPS final rule with comment period for CY 2004 (68 FR 63443)). We do not make separate payment for supplies used in services provided under the OPPS. Payments for necessary supplies are packaged into payments for the separately payable services provided by the hospital. Specifically, administration of unlabeled tositumomab is a complete service that qualifies for separate payment under its own clinical APC. This complete service

is currently described by HCPCS code G3001. Therefore, we do not agree with the commenter's recommendation that we should assign a separate HCPCS code to the supply of unlabeled tositumomab. Rather, we will continue to make separate payment for the administration of tositumomab, and payment for the supply of unlabeled tositumomab is packaged into the administration payment.

After consideration of the public comments received and the recommendations of the APC Panel, we are finalizing our proposal to provide payment for nonpass-through drugs and biologicals based on costs calculated from hospital claims, with modification to provide a 1-year transitional rate of ASP+4 percent for CY 2009. Moreover, we are not finalizing our proposal to split the single standard drug cost center into two cost centers. Instead, we will continue to explore other potential approaches to improving our drug cost estimation to improve payment accuracy for separately payable drugs and biologicals. Furthermore, we did not propose to adopt and, therefore, are not implementing the use of regression-based CCRs for cost estimation in any area of the CY 2009 OPPS, including drugs requiring detail coding and IV solutions.

c. Payment for Blood Clotting Factors

For CY 2008, we are providing payment for blood clotting factors under the OPPS at ASP+5 percent, plus an additional payment for the furnishing fee that is also a part of the payment for blood clotting factors furnished in physicians' offices under Medicare Part B. The CY 2008 updated furnishing fee increased by 4.0 percent to $0.158 per unit.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41492), we proposed to pay for blood clotting factors at ASP+4 percent, consistent with our proposed payment policy for other nonpass-through separately payable drugs and biologicals, and to continue our policy for payment of the furnishing fee using an updated amount for CY 2009. 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 were published, we were not able to include the actual updated furnishing fee in the 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 will 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/*.

Comment: Many commenters supported the CY 2009 OPPS proposal to continue to provide a furnishing fee for blood clotting factors. Several commenters requested that CMS provide payment for blood clotting factors at a rate of ASP+6 percent, in addition to providing the furnishing fee.

Response: We see no compelling reason to provide payment for blood clotting factors under a different methodology for OPPS purposes at this time. We believe that the payment rate of ASP+4 percent that we are finalizing for payment of all separately payable drugs and biologicals in CY 2009, and the additional blood clotting factor furnishing fee, are appropriate and will not jeopardize access to these treatments in the hospital outpatient setting.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to provide payment for blood clotting factors under the same methodology as other separately payable drugs and biologicals under the OPPS and to continue paying an updated furnishing fee.

4. Payment for Therapeutic Radiopharmaceuticals

a. Background

Section 303(h) of Public Law 108–173 exempted radiopharmaceuticals from ASP pricing in the physician's office setting. Beginning in the CY 2005 OPPS final rule with comment period, we have exempted radiopharmaceutical manufacturers from reporting ASP data 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 previous years' OPPS ratesetting. 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. Radiopharmaceuticals also are subject to the policies affecting all similarly classified OPPS drugs and biologicals, such as pass-through payment for diagnostic and therapeutic radiopharmaceuticals and individual packaging determinations for therapeutic radiopharmaceuticals, discussed earlier in this final rule with comment period.

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. In addition, in the CY 2006 final rule with comment period (70 FR 68654), we instructed hospitals to include charges for radiopharmaceutical handling in their charges for the radiopharmaceutical products so these costs would be reflected in the CY 2008 ratesetting process. We note that this continues to be our expectation, and we believe that the charges for radiopharmaceuticals in the CY 2007 claims data that we are using for this final rule with comment period reflect both the acquisition cost of the radiopharmaceutical and its associated overhead. The methodology of providing separate payment based on the individual hospital's overall CCR for CYs 2006 and 2007 was finalized as an interim proxy for average acquisition cost because of the unique circumstances associated with providing radiopharmaceutical products to Medicare beneficiaries. The single OPPS payment represented Medicare payment for both the acquisition cost of the radiopharmaceutical and its associated handling costs.

During the CY 2006 and CY 2007 rulemaking processes, we encouraged hospitals and radiopharmaceutical stakeholders to assist us in developing a viable long-term prospective payment methodology for these products under the OPPS. As reiterated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66766), we were pleased to note that we had many discussions with interested parties regarding the availability and limitations of radiopharmaceutical cost data.

In considering payment options for therapeutic radiopharmaceuticals for CY 2008, we examined several alternatives that we discussed in our CY 2008 OPPS/ASC proposed rule (72 FR 42738 through 42739) and CY 2008 OPPS/ASC final rule with comment period (72 FR 66769 through 66770). (We refer readers to these rules for a full discussion of all of the options that we considered.) After considering the options and the public

comments received, we finalized a CY 2008 methodology to provide a 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 are 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 are unavailable (72 FR 66772). In addition, we finalized a policy to package payment for all diagnostic radiopharmaceuticals (defined as Level II HCPCS codes that include the term ''diagnostic'' along with a radiopharmaceutical in their long code descriptors) for CY 2008. As discussed in the CY 2008 OPPS/ASC proposed rule (72 FR 42739), we believed that adopting prospective payment based on historical hospital claims data was appropriate because it served as our most accurate available proxy for the average hospital acquisition cost of separately payable therapeutic radiopharmaceuticals. In addition, we noted that we have found that our general prospective payment methodology based on historical hospital claims data results in more consistent, predictable, and equitable payment amounts across hospitals and likely provides incentives to hospitals for efficiently and economically providing these outpatient services.

Prior to implementation of our finalized CY 2008 methodology of providing a prospective payment for therapeutic radiopharmaceuticals, section 106(b) of Public Law 110–173 was enacted on December 29, 2007, that provided payment for therapeutic radiopharmaceuticals based on individual hospital charges adjusted to cost. Therefore, hospitals continue to receive payment for therapeutic radiopharmaceuticals by applying the hospital-specific overall CCR to each hospital's charge for a therapeutic radiopharmaceutical from January 1, 2008 through June 30, 2008. As we stated in the CY 2009 OPPS/ASC proposed rule, thereafter, the OPPS would provide payment for separately payable therapeutic radiopharmaceuticals on a prospective basis, with payment rates based upon mean costs from hospital claims data as set forth in the CY 2008 OPPS/ASC final rule with comment period, unless otherwise required by law.

Following issuance of the CY 2009 OPPS/ASC proposed rule, section 142 of Public Law 110–275 amended section 1833(t)(16)(C) of the Act, as amended by section 106(a) of Public Law 110–173, to further extend the payment period for therapeutic radiopharmaceuticals based on hospitals' charges adjusted to cost through December 31, 2009. Therefore, we have continued to pay hospitals for therapeutic radiopharmaceuticals at charges adjusted to cost through the remainder of CY 2008.

b. Payment Policy

Since the start of the temporary cost-based payment methodology for radiopharmaceuticals in CY 2006, we have met with several interested parties on a number of occasions regarding payment under the OPPS for radiopharmaceuticals and have received numerous different suggestions from these stakeholders regarding payment methodologies that we could employ for future use under the OPPS.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66771), we solicited comments requesting interested parties to provide information related to if and how the existing ASP methodology could be used to establish payment for specific therapeutic radiopharmaceuticals under the OPPS. We received several responses to our request for comments.

Similar to the recommendations we received during the CY 2008 OPPS/ASC proposed rule comment period (72 FR 66770), we received several suggestions regarding the establishment of an OPPS-specific methodology for radiopharmaceutical payment that would be similar to the ASP methodology, without following the established ASP procedures referenced at section 1847A of the Act and implemented through rulemaking. Some commenters recommended using external data submitted by a variety of sources other than manufacturers. Along this line, the commenters suggested gathering information from nuclear pharmacies using methodologies with a variety of names such as Nuclear Pharmacy Calculated Invoiced Price (Averaged) (CIP) and Calculated Pharmacy Sales Price (CPSP). Other commenters recommended that CMS base payment for certain radiopharmaceuticals on manufacturer-reported ASP.

As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66771), a ratesetting approach based on external data would be administratively burdensome for us because we would be required to collect, process, and review external information to ensure that the information was valid, reliable, and representative of a diverse group of hospitals and, therefore, could be used to establish rates for all hospitals. However, we specifically requested additional comments regarding the use of the existing ASP reporting structure for therapeutic radiopharmaceuticals as this established methodology is already used for payment of other drugs provided in the hospital outpatient setting (72 FR 66771). While we received several recommendations from commenters on the CY 2008 OPPS/ASC final rule with comment period regarding payment of therapeutic radiopharmaceuticals based on estimated costs provided by manufacturers or other parties, we believe that the use of external data for payment of therapeutic radiopharmaceuticals should only be adopted if those external data are subject to the same well-established regulatory framework as the ASP data currently used for payment of separately payable drugs and biologicals under the OPPS. We have previously indicated that nondevice external data used for setting payment rates should be publicly available and representative of a diverse group of hospitals both by location and type. In addition, nondevice external data sources also would have to be identified. We do not believe that external therapeutic radiopharmaceutical cost data voluntarily provided outside of the established ASP methodology, either by manufacturers or nuclear pharmacies, would generally satisfy these criteria that are minimum standards for setting OPPS payment rates.

As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66770), at its September 2007 meeting, the APC Panel recommended that CMS create a composite APC for Bexxar or related therapies and present it for the APC Panel's consideration at the next APC Panel meeting. We accepted this recommendation and modeled a radioimmunotherapy (RIT) composite APC for both Bexxar and Zevalin therapies using our final rule CY 2008 claims database. We discussed this analysis with the APC Panel at its March 2008 meeting.

To perform this analysis for the APC Panel, we first identified all claims that had an occurrence of a case-defining therapeutic radiopharmaceutical HCPCS code used for a RIT treatment: A9545 (Iodine I–131 tositumomab, therapeutic, per treatment dose) and A9543 (Yttrium Y–90 ibritumomab tiuxetan, therapeutic, per treatment dose, up to 40 millicuries). We then identified what we considered to be the HCPCS codes for services and products associated with RIT, based on information from the

manufacturers and suggestions from CMS medical advisors and identified associated claims (using beneficiary health insurance claim (HIC) numbers) to develop the total median cost for a RIT composite APC.

We note that very few hospitals billed all of the HCPCS codes for an individual beneficiary that we expected to be reported for a case of RIT treatment. We used this ''HIC-linked'' file consisting of all associated claims for each beneficiary from one hospital that we considered to be part of a single case of RIT treatment to develop a composite APC cost estimate for a course of RIT treatment, where a case required: (1) HCPCS code A9545 or A9543; (2) a HCPCS code for either nonradiolabeled tositumomab (G3001 (Administration or supply of tositumomab, 450 mg)) or rituximab (J9310 (Rituximab, 100 mg)) (which also would indicate the start of a RIT case); (3) a HCPCS code for the corresponding diagnostic radiopharmaceutical (A9544 (Iodine I–131 tositumomab, diagnostic, per study dose) or A9542 (Indium In-111, ibritumomab tiuxetan, diagnostic, per study dose, up to 5 millicuries)); and (4) at least one instance of a diagnostic imaging service (CPT code 78804 (Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring two or more days imaging)) prior to the administration of the therapeutic radiopharmaceutical. In addition, in order to further define the case for an estimate of a composite APC cost, we did not include the costs of services occurring on dates before the provision of the nonradiolabeled tositumomab or rituximab or after the administration of the therapeutic radiopharmaceutical.

Other services we expected to be reported for a case, such as CPT code 79403 (Radiopharmaceutical therapy, radiolabeled monoclonal antibody by intravenous infusion) and CPT code 77300 (Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician), were considered optional and, although they were not required in order to determine the RIT case, the costs of these associated services were included when we established the median cost of the RIT composite APC.

We determined that the median cost for the RIT composite APC, including required and optional additional services directly related to the RIT treatment, would be approximately $19,000. This figure represents, at a minimum, the estimated cost of the nonradiolabeled tositumomab (or rituximab), the diagnostic radiopharmaceutical, the therapeutic radiopharmaceutical, and the imaging, based on costs from hospital claims data.

Upon review of this study, the APC Panel, at its March 2008 meeting, recommended that CMS pursue a RIT composite APC that uses existing claims and stakeholder data to establish appropriate payment rates for RIT protocols. In addition, the APC Panel recommended that CMS provide specific guidance to hospitals on appropriate billing for RIT under a composite APC methodology. As we discussed in the CY 2009 OPPS/ASC proposed rule (73 FR 41495), we are not accepting these recommendations of the APC Panel. First, we do not believe it would be appropriate to incorporate external data into a composite APC methodology, when composite APC median costs for a comprehensive service that the composite APC describes are based upon reported hospital costs on claims as described in section II.A.2.e. of this final rule with comment period. As we have hospital costs from CY 2007 claims for the services that would be paid through a RIT composite APC, we would have no reason to use external stakeholder data instead of reported hospital costs for ratesetting for such an APC. In addition, as the APC Panel alluded to in its second recommendation regarding billing guidance to hospitals, our claims analysis demonstrated that, according to hospital claims data, apparently few patients actually received all the component services associated with RIT treatment from a single hospital, or many RIT treatments were incorrectly reported by hospitals. A composite APC payment provides more accurate payment for a set of major services with only limited variation from hospital to hospital or from case to case and relies on correctly coded claims for the comprehensive service to develop the composite cost, whereas RIT treatment does not appear to have these characteristics. Stakeholders have confirmed that a proportion of patients receiving a diagnostic radiopharmaceutical and imaging in preparation for RIT treatment do not go on to receive the therapeutic radiopharmaceutical for a variety of specific clinical reasons. Furthermore, the whole course of RIT treatment may occur over a several week period, and the challenges associated with instructing hospitals to report component services in a timely fashion that would allow the I/OCE to determine whether a composite payment would be appropriate are significant. Therefore, as we proposed, we believe it would be premature to make payment of a composite APC for RIT treatment for CY 2009.

We received comments on the CY 2008 OPPS/ASC final rule with comment period from certain radiopharmaceutical manufacturers who indicated that the standard ASP methodology could be used for payment of certain therapeutic radiopharmaceutical products. Specifically, these manufacturers expressed interest in providing ASP for their therapeutic radiopharmaceutical products as a basis for payment under the OPPS. We appreciate the willingness of these manufacturers to provide ASP data, but we recognize that payment based on the ASP methodology may not be possible for all therapeutic radiopharmaceuticals if manufacturers are unable or unwilling to voluntarily submit ASP data. Therefore, in the CY 2009 OPPS/ASC proposed rule, we proposed the following payment methodology for therapeutic radiopharmaceuticals under the CY 2009 OPPS. For therapeutic radiopharmaceuticals where ASP information is submitted through the established ASP process by all manufacturers of the specific therapeutic radiopharmaceutical, we proposed to provide payment for the average acquisition and associated handling costs of the therapeutic radiopharmaceutical at the same relative ASP-based amount (proposed at ASP+4 percent for CY 2009) that we would pay for separately payable drugs and biologicals in CY 2009 under the OPPS. If sufficient ASP information is not submitted or appropriately certified by the manufacturer for a given calendar year quarter, for that quarter we proposed that the OPPS would provide a prospective payment based on the mean cost from hospital claims data as displayed in Table 25 of the proposed rule, as this was the methodology finalized in the CY 2008 OPPS/ASC final rule with comment period. Further, we proposed to continue the methodology, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66772), of eliminating claims from providers that consistently (more than 2 times) reported charges in the CY 2007 claims data that were less than $100 when converted to costs for HCPCS codes A9543 and A9545 as part of the usual

ratesetting process. We believed that this would mitigate the effects of using incorrectly coded claims from several providers in our standard ratesetting methodology which calculates the mean costs for these two products from the claims available for the update year.

Because we did not have ASP data for therapeutic radiopharmaceuticals that were used for payment in April 2008, the proposed payment rates included in Addenda A and B to the proposed rule were based on mean costs from historical hospital claims data available for the proposed rule. Under our proposal that would initially look to ASP data to establish the payment rates for separately payable therapeutic radiopharmaceuticals, beginning in CY 2009, we proposed to update the payment rates for therapeutic radiopharmaceuticals quarterly as new ASP data become available, just as we would update the payment rates for separately payable drugs and biologicals under the OPPS.

We proposed to allow manufacturers to submit ASP information for any separately payable therapeutic radiopharmaceutical for payment purposes under the OPPS. However, we did not propose to compel manufacturers to submit ASP information. The ASP data submitted would need to be provided for a patient-specific dose, or patient-ready form, of the therapeutic radiopharmaceutical in order to properly calculate the ASP amount for a given HCPCS code. In addition, in those instances where there is more than one manufacturer of a particular therapeutic radiopharmaceutical, we noted that all manufacturers would need to submit ASP information in order for payment to be made on an ASP basis. In the proposed rule, we specifically requested public comment on the development of a crosswalk, similar to the NDC/HCPCS crosswalk for separately payable drugs and biologicals posted on the CMS Web site at: *http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a_2008aspfiles.asp*, for use for therapeutic radiopharmaceuticals. We believed that the use of ASP information for OPPS payment would provide an opportunity to improve payment accuracy for these products by applying an established methodology that has already been successfully implemented under the OPPS for other separately payable drugs and biologicals. As is the case with other drugs and biologicals subject to ASP reporting, in order for a therapeutic radiopharmaceutical to receive payment based on ASP beginning January 1, 2009, we would need to receive ASP information from the manufacturer in October 2008 that would reflect therapeutic radiopharmaceutical sales in the third quarter of CY 2008 (July 1, 2008 through September 30, 2008). We indicated that these data would not be available for publication in this CY 2009 OPPS/ASC final rule with comment period but would be included in the January 2009 OPPS quarterly release that would update the payment rates for separately payable drugs, biologicals, and therapeutic radiopharmaceuticals based on the most recent ASP data, consistent with our customary practice over the past 3 years when we have used the ASP methodology for payment of separately payable drugs and biologicals under the OPPS. In addition, we indicated our need to receive information from radiopharmaceutical manufacturers that would allow us to calculate a unit dose cost estimate based on the applicable HCPCS code for the therapeutic radiopharmaceutical.

We realize that not all therapeutic radiopharmaceutical manufacturers may be willing or able to submit ASP information for a variety of reasons. We proposed to provide payment at the ASP rate if ASP information is available for a given calendar year quarter or, if ASP information is not available, we proposed to provide payment based on the most recent hospital mean unit cost data that we have available. We believed that both methodologies represented an appropriate and adequate proxy for average hospital acquisition cost and associated handling costs for these products. Therefore, if ASP information for the appropriate period of sales related to payment in any CY 2009 quarter was not available, we would rely on the CY 2007 mean unit cost data derived from hospital claims to set the payment rates for therapeutic radiopharmaceuticals. We noted that this is not the usual OPPS process that relies on alternative data sources, such as WAC or AWP, when ASP information is temporarily unavailable, prior to defaulting to the mean unit cost from hospital claims data. We proposed to use this methodology specifically for therapeutic radiopharmaceuticals whereby we would immediately default to the mean unit cost from hospital claims if sufficient ASP data were not available because we were not proposing to require therapeutic radiopharmaceutical manufacturers to report ASP data at this time. We did not believe that WAC or AWP would be an appropriate proxy for OPPS payment for average therapeutic radiopharmaceutical acquisition cost and associated handling costs when manufacturers would not be required to submit ASP data and, therefore, payment based on WAC or AWP could continue for the full calendar year. We remind readers that WAC or AWP provide temporary payment rates for drugs under the umbrella of the general ASP methodology, and these are typically used while we are awaiting ASP information on actual sales prices to be submitted by drug manufacturers. We do not believe that it would be most appropriate to provide payment through WAC or AWP on a long-term basis for radiopharmaceuticals sold by those manufacturers that choose not to or cannot submit ASP information.

Similar to the ASP process already in place for drugs and biologicals, we proposed to update ASP data for therapeutic radiopharmaceuticals through our quarterly process as updates become available. In addition, we proposed to assess the availability of ASP data for therapeutic radiopharmaceuticals quarterly, and if ASP data became available midyear, we would transition at the next available quarter to ASP-based payment. For example, if ASP data were not available for the quarter beginning January 2009 (that is, ASP information reflective of third quarter CY 2008 sales are not submitted in October 2008), the next opportunity to begin payment based on ASP data for a therapeutic radiopharmaceutical would be April 2009 if ASP data reflective of fourth quarter CY 2008 sales were submitted in January 2009.

Comment: Several commenters supported CMS' proposal to provide payment for therapeutic radiopharmaceuticals based on the ASP methodology. While some commenters acknowledged that ASP reporting may not be possible for all therapeutic radiopharmaceutical manufacturers, several commenters noted their intent to begin providing CMS with ASP data for specific therapeutic radiopharmaceuticals in CY 2009.

Finally, while many commenters noted that Public Law 110–275 would not allow the proposed ASP methodology to be adopted for CY 2009, many commenters urged CMS to consider this methodology for CY 2010 and beyond.

Response: We appreciate the support for our proposal to provide payment for therapeutic radiopharmaceuticals based on the ASP methodology for CY 2009. However, as the commenters noted, Public Law 110–275 has directed us to provide payment for therapeutic radiopharmaceuticals at hospital charges adjusted to cost throughout CY 2009. Therefore, our CY 2009 payment methodology for therapeutic

radiopharmaceuticals will be made in accordance with the statutory requirements. However, we appreciate the comments on the use of the ASP methodology and will consider them as we proceed with our CY 2010 ratesetting process.

After consideration of the public comments received, and taking into account the requirements of Public Law 110–275, we are finalizing a policy to provide payment for all therapeutic radiopharmaceuticals listed in Table 29 below at hospital charges adjusted to cost for CY 2009. These therapeutic radiopharmaceuticals are assigned status indicator ''H'' in Addendum B to this final rule with comment period, as discussed in section XIII.A. of this final rule with comment period. As described earlier, we are continuing to define therapeutic radiopharmaceuticals as those radiopharmaceuticals that contain the word ''therapeutic'' in their long HCPCS codes descriptors.

TABLE 29—CY 2009 THERAPEUTIC RADIOPHARMACEUTICALS PAID AT CHARGES ADJUSTED TO COST

CY 2009 HCPCS code	CY 2009 short descriptor	Final CY 2009 APC	Final CY 2009 SI
A9517	I131 iodide cap, rx	1064	H
A9530	I131 iodide sol, rx	1150	H
A9543	Y90 ibritumomab, rx	1643	H
A9545	I131 tositumomab, rx	1645	H
A9563	P32 Na phosphate	1675	H
A9564	P32 chromic phosphate	1676	H
A9600	Sr89 strontium	0701	H
A9605	Sm 153 lexidronm	0702	H

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes, but Without OPPS Hospital Claims Data

Public Law 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 and biologicals 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, 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 CY 2008, we finalized a policy to provide payment for new drugs and biologicals with HCPCS codes but which did not have pass-through status and were without OPPS hospital claims data, at ASP+5 percent, consistent with the final OPPS payment methodology for other separately payable drugs and biologicals. In the CY 2009 OPPS/ASC proposed rule (73 FR 41496), we proposed to continue this methodology for CY 2009. Therefore, for CY 2009, we proposed to provide payment for new drugs and biologicals with HCPCS codes, but which do not have pass-through status and are without OPPS hospital claims data, at ASP+4 percent, consistent with the CY 2009 proposed payment methodology for other separately payable nonpass-through drugs and biologicals. We believed that this policy would ensure that new nonpass-through drugs and biologicals would be treated like other drugs and biologicals under the OPPS, unless they are granted pass-through status. Only if they are pass-through drugs and biologicals would they receive a different payment for CY 2009, 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 proposed to continue packaging payment for all new nonpass-through diagnostic radiopharmaceuticals in CY 2009.

In accordance with the ASP methodology, in the absence of ASP data, we proposed, for CY 2009, 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 were without OPPS claims data. However, we noted that if the WAC was also unavailable, we would make payment at 95 percent of the product's most recent AWP. We also proposed to assign status indicator ''K'' to HCPCS codes for new drugs and biologicals for which we had not received a pass-through application. We further noted that, with respect to new items for which we did not have ASP data, once their ASP data became 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 2009 at ASP+4 percent) for items that had not been granted pass-through status. Furthermore, we proposed to package payment for new HCPCS codes that describe nonpass-through biologicals that are only implantable, as discussed further in section V.A.2. of this final rule with comment period.

For CY 2009, we also proposed to base payment for new therapeutic radiopharmaceuticals with HCPCS codes as of January 1, 2009, but which did not have pass-through status, on the WACs for these products if ASP data for these therapeutic radiopharmaceuticals were not available. If the WACs were also unavailable, we proposed to make payment for new therapeutic radiopharmaceuticals at 95 percent of their most recent AWPs because we would not have mean costs from hospital claims data upon which to base payment. Analogous to new drugs and biologicals, we proposed to assign status indicator ''K'' to HCPCS codes for new therapeutic radiopharmaceuticals for which we had not received a pass-through application.

Consistent with other ASP-based payments, for CY 2009, we proposed to make any appropriate adjustments to the payment amounts for new drugs and biologicals in this CY 2009 OPPS/ASC final rule with comment period and also on a quarterly basis on our Web site during CY 2009 if later quarter ASP submissions (or more recent WACs or AWPs) indicated that adjustments to the payment rates for these drugs and

biologicals were necessary. The payment rates for new therapeutic radiopharmaceuticals would also be adjusted accordingly. We noted in the proposed rule that the new CY 2009 HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals were not available at the time of development of the proposed rule. We indicated that they would be included in this CY 2009 OPPS/ASC final rule with comment period where they are assigned comment indicator ''NI'' to reflect that their interim final OPPS treatment is open to public comment in the CY 2009 OPPS/ASC final rule with comment period.

We did not receive any public comments specific to these CY 2009 proposals. Therefore, we are finalizing these proposals, with the following modification regarding payment for nonpass-through therapeutic radiopharmaceuticals. In accordance with Public Law 110–275, OPPS payment for nonpass-through therapeutic radiopharmaceuticals is made based on hospital charges adjusted to cost for CY 2009.

There are several nonpass-through drugs and biologicals that were payable in CY 2007 and/or CY 2008 for which we did not have any CY 2007 hospital claims data available for the CY 2009 proposed rule. In order to determine the packaging status of these items for CY 2009, 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+4 percent, similar to other nonpass-through drugs and biologicals paid separately under the OPPS, by an estimated average number of units of each product that would typically be furnished to a patient during one administration in the hospital outpatient setting. We proposed to package items for which we estimated the per administration cost to be less than or equal to $60, which is the general packaging threshold that we proposed for drugs, biologicals, and therapeutic radiopharmaceuticals in CY 2009. We proposed to pay separately for items with an estimated per administration cost greater than $60 (with the exception of diagnostic radiopharmaceuticals and contrast agents which we proposed to continue to package regardless of cost, as discussed in more detail in section V.B.2.c. of this final rule with comment period) in CY 2009. We proposed that the CY 2009 payment for separately payable items without CY 2007 claims data would be based on ASP+4 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 proposed to use the WAC for the product to establish the initial payment rate. However, we noted that if the WAC was also unavailable, we would make payment at 95 percent of the most recent AWP available.

We did not receive any public comments on this CY 2009 proposal. Therefore, we are finalizing the proposal, without modification.

Table 30 lists all of the nonpass-through drugs and biologicals without available CY 2007 claims data to which these policies apply in CY 2009.

TABLE 30—DRUGS AND BIOLOGICALS WITHOUT CY 2007 CLAIMS DATA

CY 2008 HCPCS code	CY 2009 HCPCS code	CY 2009 short descriptor	Estimated average number of units per administration	Final CY 2009 SI	Final CY 2009 APC
C9237	J1930	Lanreotide injection	90	K	9237
J0400	J0400	Aripiprazole injection	39	N	
J2724	J2724	Protein c concentrate	630	K	1139
J3355	J3355	Urofollitropin, 75 iu	2	K	1741
Q4096	J7186	Antihemophilic viii/VWF comp	6825	K	1213

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66776), we began recognizing, for OPPS payment purposes, multiple HCPCS codes indicating different dosages for covered Part B drugs. In general, prior to CY 2008, the OPPS recognized the lowest available administrative dose of a drug if multiple HCPCS codes existed for the drug; for the remainder of the doses, the HCPCS codes were assigned status indicator ''B'' indicating that another code existed for OPPS purposes. For example, if drug X has 2 HCPCS codes, 1 for a 1 ml dose and a second for a 5 ml dose, prior to CY 2008, the OPPS would have assigned a payable status indicator to the 1 ml dose and status indicator ''B'' to the 5 ml dose. Hospitals were then responsible for billing the appropriate number of units for the 1 ml dose in order to receive payment for the drug under the OPPS.

As these HCPCS codes were previously unrecognized under the OPPS prior to CY 2008, we do not have claims data to determine their appropriate packaging status for CY 2009. For the CY 2008 OPPS/ASC final rule with comment period (72 FR 66775), we implemented a policy that assigned the status indicator of the previously recognized HCPCS code to the associated newly recognized code(s). For CY 2009, we proposed to continue to use this methodology.

Table 31 below shows the previously unrecognized HCPCS code, the previous status indicator for the unrecognized HCPCS code, the CY 2009 short descriptor for the previously unrecognized HCPCS code, the associated recognized HCPCS code, and the status indicator for the newly recognized code. As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66775), we believed that this approach would be the most appropriate and reasonable way to implement this change in HCPCS code recognition under the OPPS without impacting payment. However, we noted that once claims data are 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 code-specific methodology for determining a code's packaging status for a given update year. As we stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66775), we plan to closely follow our claims data to ensure that our annual packaging determinations for the different HCPCS codes describing the same drug do not create inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others.

Comment: One commenter requested that we recognize HCPCS codes Q0165 (Prochlorperazine maleate, 10 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen);

Q0168 (Dronabinol, 5 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen); Q0170 (Promethazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen); Q0172 (Chlorpromazine hydrochloride, 25 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen); 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); and Q0178 (Hydroxyzine pamoate, 50 mg, oral, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48-hour dosage regimen) that currently have OPPS status indicators of ''B,'' but that have related HCPCS codes for the same drugs with different dosages and that are recognized for payment under the OPPS.

Response: We appreciate the commenter identifying these additional HCPCS codes, and we agree that we should recognize these HCPCS codes for drugs that are payable under the OPPS in order to allow hospital to report all HCPCS codes for drugs. As we concluded for the drug HCPCS codes that that we newly recognized for CY 2008, we believe that recognizing all of these HCPCS codes for payment under the OPPS should not have a significant effect on our payment methodology for drugs. Stakeholders have told us that this policy reduces the administrative burden associated with hospitals' reporting of only the HCPCS code with the lowest increment in its code descriptor for the OPPS. Wherever possible and appropriate, we continue to seek to reduce hospitals' administrative burden in submitting claims for payment under the OPPS. In determining the packaging status of these HCPCS drug codes for CY 2009, we are following the methodology we implemented in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66725), and we have assigned them the same status indicators as the associated currently recognized HCPCS codes under the OPPS.

We are recognizing these additional 6 HCPCS codes under the OPPS, effective January 1, 2009. These codes are included in Table 31 below and identified with an (*) to denote that they are newly recognized in CY 2009, while the other HCPCS drug codes displayed in the table were newly recognized in CY 2008.

After consideration of the public comment received, we are finalizing our CY 2009 proposal to provide payment for newly recognized HCPCS drug codes for different doses of the same drugs on the same basis as the previously recognized HCPCS codes for those drugs, with modification to apply this policy to six additional HCPCS drug codes.

TABLE 31—HCPCS CODES UNRECOGNIZED IN CY 2007 OR CY 2008, ASSOCIATED RECOGNIZED HCPCS CODES, AND STATUS INDICATORS FOR CY 2009

CY 2009 HCPCS codes previously unrecognized	CY 2007 SI	CY 2009 short descriptor	Associated HCPCS recognized in CY 2007	Final CY 2009 SI for newly recognized HCPCS code
J1470	B	Gamma globulin 2 CC inj	J1460	K
J1480	B	Gamma globulin 3 CC inj	J1460	K
J1490	B	Gamma globulin 4 CC inj	J1460	K
J1500	B	Gamma globulin 5 CC inj	J1460	K
J1510	B	Gamma globulin 6 CC inj	J1460	K
J1520	B	Gamma globulin 7 CC inj	J1460	K
J1530	B	Gamma globulin 8 CC inj	J1460	K
J1540	B	Gamma globulin 9 CC inj	J1460	K
J1550	B	Gamma globulin 10 CC inj	J1460	K
J1560	B	Gamma globulin >10 CC inj	J1460	K
J8521	B	Capecitabine, oral, 500 mg	J8520	K
J9062	B	Cisplatin 50 MG injection	J9060	N
J9080	B	Cyclophosphamide 200 MG inj	J9070	N
J9090	B	Cyclophosphamide 500 MG inj	J9070	N
J9091	B	Cyclophosphamide 1.0 grm inj	J9070	N
J9092	B	Cyclophosphamide 2.0 grm inj	J9070	N
J9094	B	Cyclophosphamide lyophilized	J9093	N
J9095	B	Cyclophosphamide lyophilized	J9093	N
J9096	B	Cyclophosphamide lyophilized	J9093	N
J9097	B	Cyclophosphamide lyophilized	J9093	N
J9110	B	Cytarabine hcl 500 MG inj	J9100	N
J9140	B	Dacarbazine 200 MG inj	J9130	N
J9260	B	Methotrexate sodium inj	J9250	N
J9290	B	Mitomycin 20 MG inj	J9280	N
J9291	B	Mitomycin 40 MG inj	J9280	N
J9375	B	Vincristine sulfate 2 MG inj	J9370	N
J9380	B	Vincristine sulfate 5 MG inj	J9370	N
Q0165*	B	Prochlorperazine maleate 10 mg	Q0164	N
Q0168*	B	Dronabinol 5 mg oral	Q0167	N
Q0170*	B	Promethazine HCl 25 mg oral	Q0169	N
Q0172*	B	Chlorpromazine HCl 25 mg oral	Q0171	N
Q0176*	B	Perphenazine 8 mg oral	Q0175	N

TABLE 31—HCPCS CODES UNRECOGNIZED IN CY 2007 OR CY 2008, ASSOCIATED RECOGNIZED HCPCS CODES, AND STATUS INDICATORS FOR CY 2009—Continued

CY 2009 HCPCS codes previously unrecognized	CY 2007 SI	CY 2009 short descriptor	Associated HCPCS recognized in CY 2007	Final CY 2009 SI for newly recognized HCPCS code
Q0178 *	B	Hydroxyzine pamoate 50 mg	Q0177	N

* Denotes newly recognized HCPCS code for the CY 2009 OPPS.

Finally, there were eight drugs and biologicals, shown in Table 28 of the proposed rule, that were payable in CY 2007 but for which we lacked CY 2007 claims data and any other data related to the ASP methodology and, therefore, we were unable to determine their per day cost based on the ASP methodology. As we were unable to determine the packaging status and subsequent payment rates, if applicable, for these drugs and biologicals for CY 2009 based on the ASP methodology and/or claims data, we proposed to package payment for these drugs and biologicals in CY 2009.

HCPCS code J0395 (Arbutamine HCl injection) did not have any data for the CY 2009 OPPS/ASC proposed rule. However, as a result of updated data used for this final rule with comment period, we received hospital claims data for this code and are, therefore, able to make a packaging determination for the drug for CY 2009. There was one claim for CY 2007 for HCPCS code J0395, with a per day cost estimate of approximately $58. Therefore, because this amount is below our final drug packaging threshold for CY 2009, we are packaging HCPCS code J0395.

We did not receive any public comments on our proposal to package payment for drugs that were payable in CY 2007 but for which we lack CY 2007 claims data and for which we are unable to determine the estimated per day cost based on the ASP methodology. Therefore, we are finalizing our CY 2009 proposal, with modification to exclude HCPCS code J0395 from packaging based on this rationale, to package payment for the seven drugs and biologicals listed in Table 32 below, due to missing data essential to calculating a per day cost. We are packaging payment for HCPCS code J0395 on the basis of an estimated per day cost of less than the final CY 2009 OPPS drug packaging threshold.

TABLE 32—DRUGS AND BIOLOGICALS WITHOUT INFORMATION ON PER DAY COST AND THAT ARE PACKAGED IN CY 2009

CY 2009 HCPCS code	CY 2009 short descriptor	Final CY 2009 SI
90393	Vaccina ig, im	N
90581	Anthrax vaccine, sc	N
J0350	Injection anistreplase 30 u.	N
J1452	Intraocular Fomivirsen na.	N
J2670	Totazoline hcl injection.	N
J3530	Nasal vaccine inhalation.	N
Q0174	Thiethylperazine maleate 10 mg.	N

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

A. Background

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an ''applicable percentage'' of total program payments estimated to be made under 1833(t) of the Act for all covered services furnished for that year under the hospital OPPS. For a year before CY 2004, the applicable percentage was 2.5 percent; for CY 2004 and subsequent years, we specify the applicable percentage up to 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.

For devices, developing an estimate of pass-through spending in CY 2009 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 2009. 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 2008 or beginning in CY 2009. The sum of the CY 2009 pass-through estimates for these two groups of device categories would equal the total CY 2009 pass-through spending estimate for device categories with pass-through status.

For drugs and biologicals, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount for drugs and biologicals eligible for pass-through payment 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 finalized a policy to pay for nonpass-through separately payable drugs and biologicals under the CY 2009 OPPS at ASP+4 percent, which represents the otherwise applicable fee schedule amount associated with a pass-through drug or biological, and because we will pay for pass-through drugs and

biologicals at ASP+6 percent or the Part B drug CAP rate, if applicable, our estimate of drug and biological pass-through payment for CY 2009 is not zero. (We note that the Part B drug CAP program has been postponed for CY 2009. We refer readers to the Medicare Learning Network (MLN) Matters Special Edition article SE0833. Therefore, there will be no effective Part B drug CAP rate for pass-through drugs and biologicals as of January 1, 2009.) Similar to 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 2009. The second group contains drugs and biologicals that we know are newly eligible, or project would be newly eligible, beginning in CY 2009. The sum of the CY 2009 pass-through estimates for these two groups of drugs and biologicals would equal the total CY 2009 pass-through spending estimate for drugs and biologicals with pass-through status.

B. Estimate of Pass-Through Spending

As we proposed, in this final rule with comment period, we are finalizing a policy of setting the applicable percentage limit at 2.0 percent of the total OPPS projected payments for CY 2009, consistent with our OPPS policy from CYs 2004 through 2008.

As discussed in section IV.A. of this final rule with comment period, there are currently no known device categories receiving pass-through payment in CY 2008 that will continue for payment during CY 2009. Therefore, there are no device categories in the first group (that is, device categories recently made eligible for pass-through payment and continuing into CY 2009), and we estimated the pass-through spending to be $0 for this group in the proposed rule. For this final rule with comment period, we continue to estimate $0 for this group.

In estimating CY 2009 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 2009 (of which there were none), additional device categories that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2009, and contingent projections for new categories in the second through fourth quarters of CY 2009), we proposed to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. We estimated the CY 2009 pass-through spending for this second group to be $10 million in the proposed rule, and that continues to be our estimate for this final rule with comment period.

Employing our established methodology that the estimate of pass-through device spending in CY 2009 incorporates CY 2009 estimates of pass-through spending for known device categories continuing in CY 2009, those first effective January 1, 2009, and those device categories projected to be approved during subsequent quarters of CYs 2008 and 2009, in the proposed rule, we estimated the total pass-through spending for device categories to be $10 million for CY 2009. This estimate of $10 million remains our estimate for this CY 2009 final rule with comment period.

We did not receive any public comments regarding our proposed methodology for estimating transitional pass-through spending for devices for CY 2009. Therefore, we are adopting our final estimate of $10 million for total pass-through spending for device categories for CY 2009.

To estimate CY 2009 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing into CY 2009, we proposed to utilize the most recent Medicare physician's office data regarding their utilization, information provided in the respective pass-through applications, historical hospital claims data, pharmaceutical industry information, and clinical information regarding those drugs or biologicals, in order to project the CY 2009 OPPS utilization of the products. For the known drugs and biologicals that would continue on pass-through status in CY 2009, we then estimate the total pass-through payment amount as the difference between ASP+6 percent or the Part B drug CAP rate, as applicable, and ASP+4 percent, aggregated across the projected CY 2009 OPPS utilization of these products. If payment for the drug or biological would be packaged if the product were not paid separately because of its pass-through status, we include in the pass-through estimate the full payment for the drug or biological at ASP+6 percent. Based on these analyses, our final estimate of pass-through spending attributable to the first group (that is, the known drugs and biologicals continuing with pass-through eligibility in CY 2009) described above is approximately $16.3 million for CY 2009. This $16.3 million estimate of CY 2009 pass-through spending for the first group of pass-through drugs and biologicals reflects the current pass-through drugs and biologicals that are continuing on pass-through status into CY 2009, and are displayed in Table 23 of this final rule with comment period.

To estimate CY 2009 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of the proposed rule would be newly eligible for pass-through payment in CY 2009 (of which there were none), additional drugs and biologicals that we estimate could be approved for pass-through status subsequent to the development of the proposed rule and before January 1, 2009, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2009), we used utilization estimates from applicants, pharmaceutical industry data, and clinical information as the basis for pass-through spending estimates for these drugs and biologicals for CY 2009, while also considering the most recent OPPS experience in approving new pass-through drugs and biologicals. Based on these analyses, we estimate pass-through spending attributable to this second group of drugs and biologicals to be about $7.0 million for CY 2009.

In the CY 2005 OPPS final rule with comment period (69 FR 65810), we indicated that we would be accepting pass-through applications for new radiopharmaceuticals that are assigned a HCPCS code on or after January 1, 2005. (Prior to this date, radiopharmaceuticals were not included in the category of drugs paid under the OPPS, and, therefore, were not eligible for pass-through status.) There were no radiopharmaceuticals that were eligible for pass-through payment at the time of publication of the CY 2009 OPPS/ASC proposed rule, and we have not received any pass-through applications for radiopharmaceuticals between the publication of the proposed rule and this final rule with comment period. As noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41500), we also have no historical data regarding payment for new radiopharmaceuticals with pass-through status under the methodology that we specified for the CY 2005 OPPS or the CY 2009 methodologies for diagnostic and therapeutic radiopharmaceuticals that we finalized, as discussed in section

V.A.3. of this final rule with comment period. However, we do not believe that pass-through spending for new radiopharmaceuticals in CY 2009 would be significant enough to materially affect our estimate of total pass-through spending in CY 2009. Therefore, we did not include radiopharmaceuticals in our proposed estimate of pass-through spending for CY 2009, and we have not included them in our final estimate of pass-through spending for CY 2009. We discuss our final policy regarding payment for all new diagnostic radiopharmaceuticals without pass-through status in CY 2009 in section V.B.2.c. of this final rule with comment period.

We did not receive any public comments regarding our proposed methodology for estimating transitional pass-through spending for drugs, biologicals, and radiopharmaceuticals for CY 2009. Therefore, we are adopting our final estimate of $23.3 million for total pass-through spending for drugs, biologicals, and radiopharmaceuticals for CY 2009.

In accordance with the comprehensive 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 for pass-through payment into CY 2009 and those device categories, drugs, biologicals, and radiopharmaceuticals that first become eligible for pass-through status during CY 2009 would approximate $33.3 million, which represents 0.11 percent of total OPPS projected payments for CY 2009.

We estimate that pass-through spending in CY 2009 would not amount to 2.0 percent of total projected OPPS CY 2009 program spending.

Accordingly, we are finalizing our proposed methodology for estimating CY 2009 OPPS pass-through spending for drugs, biologicals, radiopharmaceuticals, and device categories. Our final pass-through estimate for CY 2009 is $33.3 million.

VII. OPPS Payment for Brachytherapy Sources

A. Background

Section 1833(t)(2)(H) of the Act, as added by section 621(b)(2)(C) of Public Law 108–173 (MMA), mandated the creation of separate groups of covered OPD services that classify brachytherapy devices separately from other services or groups of services. The additional groups must reflect the number, isotope, and radioactive intensity of the devices of brachytherapy furnished, including separate groups for palladium-103 and iodine-125 devices.

Section 1833(t)(16)(C) of the Act, as added by section 621(b)(1) of Public Law 108–173, established payment for devices of brachytherapy consisting of a seed or seeds (or radioactive source) based on a hospital's charges for the service, adjusted to cost. The period of payment under this provision is for brachytherapy sources furnished from January 1, 2004, through December 31, 2006. Under section 1833(t)(16)(C) of the Act, charges for the brachytherapy devices may not be used in determining any outlier payments under the OPPS for that period of payment. 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 68114).

Subsequent to publication of the CY 2007 OPPS/ASC final rule with comment period, section 107(a) of the MIEA–TRHCA (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 1 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 the MIEA–TRHCA 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 devices beginning July 1, 2007. Section 107(b)(2) of the MIEA–TRHCA authorized the Secretary to implement this new requirement by ''program instruction or otherwise.'' This new requirement is in addition to the requirement for separate payment groups based on the number, isotope, and radioactive intensity of brachytherapy devices that was previously established by section 1833(t)(2)(H) of the Act. We note that 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 via 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 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, that is, C2698 (Brachytherapy source, stranded, not otherwise specified, per source) for stranded NOS sources, and 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 66783 through 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 to also 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. 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.

After we finalized our proposal to pay for brachytherapy sources in CY 2008 based on median costs, section 106(a) of

the MMSEA (Pub. L. 110–173) extended the charges-adjusted-to-cost payment methodology for brachytherapy sources for an additional 6 months, through June 30, 2008.

Status indicator ''H'' (defined in the CY 2008 OPPS/final rule with comment period as ''Pass-Through Device Categories. Separate cost-based pass-through payment; not subject to copayment.'') was continued for claims processing purposes for brachytherapy source payment through June 30, 2008, although a beneficiary copayment was applied to payment for these sources. We had finalized a policy in the CY 2008 OPPS/ASC final rule with comment period to assign status indicator ''K'' (defined as ''Nonpass-Through Drugs and Biologicals; Therapeutic Radiopharmaceuticals; Brachytherapy Sources; Blood and Blood Products. Paid under OPPS; separate APC payment.'') to all brachytherapy source APCs because the sources would be paid based on prospective payment. The definition of status indicator ''K'' was initially changed for CY 2007 to accommodate prospective payment for brachytherapy sources and this change was continued for CY 2008 (72 FR 66785). However, we never applied status indicator ''K'' to brachytherapy sources for the first 6 months of CY 2008, due to the requirements of the MMSEA.

For CY 2008, we also adopted the policy we established in the CY 2007 OPPS/ASC final rule with comment period (which was superseded by section 107 of the MIEA–TRHCA) regarding payment for new brachytherapy sources for which we have no claims data. 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 (72 FR 66785). When section 106(a) of the MMSEA extended the charges-adjusted-to-cost payment methodology for brachytherapy sources through June 30, 2008, this policy was not implemented as of January 1, 2008. We stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41501) that we anticipated implementing this policy as of July 1, 2008.

B. OPPS Payment Policy

In the CY 2009 OPPS/ASC proposed rule (73 FR 41500), we again proposed prospective payment rates for brachytherapy sources for CY 2009. We proposed to use CY 2007 claims data for setting the CY 2009 rates for brachytherapy sources, as we proposed for most other items and services that would be paid under the CY 2009 OPPS, using our standard OPPS ratesetting methodology. 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. The separately payable brachytherapy source codes, descriptors, APCs, approximate median costs, and status indicators were presented in Table 29 of the CY 2009 OPPS/ASC proposed rule.

We proposed to establish new status indicator ''U'' (Brachytherapy Sources. Paid under OPPS; separate APC payment.) for brachytherapy sources as of January 1, 2009. In the CY 2009 OPPS/ASC proposed rule, we noted that status indicator ''H'' has been used for the periods when brachytherapy sources were paid based on the charges-adjusted-to-cost payment methodology, while status indicator ''K'' was slated to be used for brachytherapy source payment as of July 1, 2008 through December 31, 2008, in accordance with the policy we finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). Status indicator ''H'' is also used for devices paid at charges adjusted to cost during their period of pass-through payment. While the CY 2008 definition of status indicator ''K'' currently encompasses nonpass-through drugs and biologicals, therapeutic radiopharmaceuticals, brachytherapy sources, and blood and blood products, brachytherapy sources have never been actually assigned this payment indicator because they have not had a period of prospective payment in CY 2008. However, assigning a status indicator to several types of items and services with potentially differing payment policies has added unnecessary complexity to our operations. In addition, in CY 2009, we are implementing section 1833(t)(17)(A) of the Act that specifies payment to hospitals based on a reduced conversion factor when those hospitals fail to submit timely hospital outpatient quality data as required. Therefore, to facilitate implementation of this payment change and streamline operations, we proposed to assign new status indicator ''U'' to brachytherapy source HCPCS codes beginning in CY 2009.

For CY 2009, we also proposed to continue the policy we established in the CY 2007 OPPS/ASC final rule with comment period (which was superseded by section 107 of the MIEA–TRHCA) regarding payment for new brachytherapy sources for which we have no claims data. In accordance with that policy, 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.

Subsequent to issuance of the CY 2009 OPPS/ASC proposed rule, Congress enacted Public Law 110–275 (MIPPA) on July 15, 2008. Section 142 of Public Law 110–275 amended section 1833(t)(16)(C) of the Act as amended by section 106(a) of the 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 have continued to pay for brachytherapy sources at charges adjusted to cost in CY 2008 from July 1 through December 31, and we have maintained the assignment of status indicator ''H'' to brachytherapy sources for claims processing purposes. Furthermore, we will continue to pay for all separately payable brachytherapy sources based on a hospital's charges adjusted to cost for CY 2009. Because brachytherapy sources will be paid at charges adjusted to cost, we will not subject them to the outlier provision of section 1833(t)(5) of the Act, or subject brachytherapy source payment weights to scaling for purposes of budget neutrality. Moreover, during this CY 2009 period of payment at charges adjusted to cost, brachytherapy sources will not be eligible for the 7.1 percent rural SCH adjustment (as discussed in detail in section II.E. of this final rule with comment period).

Comment: Several commenters expressed support for the extension of brachytherapy source payment based on charges adjusted to cost through December 31, 2009, as required by Public Law 110–275. They cited concerns regarding CMS' brachytherapy source claims data used in the CY 2009 proposal to set the prospective brachytherapy source rates based on median costs. Examples of the data concerns presented by the commenters include the following: difficulty in establishing a prospective payment rate for high dose rate (HDR) sources which can be used for multiple patients; use of only partial CY 2007 claims data for stranded sources for the CY 2009 OPPS payment; high variation in unit cost for certain brachytherapy sources; costs from few hospitals represented in claims data for certain sources; and a proposed rate for high activity palladium-131 that was lower than low activity palladium, inconsistent with

the true costs of these sources as reported by commenters. One commenter did not support prospective payment rates for brachytherapy sources for which ASP data are not available. A few commenters recommended continuation of payment based on charges adjusted to cost for CY 2010 and beyond, adopted through regulation.

One commenter stated that the highly variable claims data for yttrium-90 (C2616, Brachytherapy source, non-stranded, Yttrium-90, per source), a source which is reported by only a small number of providers, in combination with possible charge compression for this very high cost source, result in variable and inaccurate claims data and, therefore, an inadequate proposed payment rate that would not pay appropriately for the source cost to permit access for Medicare beneficiaries. The commenter asserted generally that these factors result in unpredictable and inequitable payment rates for all such sources.

Response: We appreciate the detailed public comments that describe data characteristics and will take the issues raised by the commenters into consideration in future proposed ratesetting for brachytherapy sources. As noted previously in this section, for CY 2009, section 142 of Public Law 110–275 (MIPPA) requires us to pay for brachytherapy sources at charges adjusted to costs. Therefore, we are not considering any other payment methodologies for CY 2009, and we are not adopting our CY 2009 proposal. We will make a proposal for the CY 2010 payment of brachytherapy sources in the CY 2010 OPPS/ASC proposed rule, consistent with our annual OPPS/ASC update process.

Furthermore, for CY 2009, we are not adopting 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, C2698 and C2699, based on a rate equal to the lowest stranded or non-stranded prospective payment for such sources. Also, we are not adopting the policy we established in the CY 2007 OPPS/ASC final rule with comment period regarding payment for new brachytherapy sources for which we have no claims data. NOS codes C2698 and C2699 and newly established specific source codes will be paid at charges adjusted to cost through December 31, 2009, consistent with section 142 of Public Law 110–275.

In addition, we did not receive any public comments regarding the proposed policy to create new status indicator ''U'' for brachytherapy source payment. Therefore, we are finalizing this proposal, without modification, for CY 2009. As noted earlier in this section, assigning a status indicator to several types of items and services with potentially differing payment policies has added unnecessary complexity to our operations. Status indicator ''U'' will be used only for brachytherapy sources, regardless of their specific payment methodology for any period of time. The use of status indicator ''U'' is expected to eliminate the complexity in the payment of brachytherapy sources caused by using status indicator ''K'' for multiple types of items and services.

In summary, for CY 2009, we will continue to pay for all brachytherapy sources, assigned status indicator ''U,'' at charges adjusted to cost, consistent with section 142 of Public Law 110–275, by the overall hospital CCR on a claim-specific basis. All currently established brachytherapy source HCPCS codes that will be paid under the CY 2009 OPPS are listed in Table 33 below, along with their corresponding APCs and status indicator assignments.

In our CY 2009 OPPS/ASC proposed rule (73 FR 41503), we again invited 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. We indicated that we would continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

Comment: One commenter recommended that CMS establish a new HCPCS code specifically for high activity cesium-131, with a descriptor of ''Brachytherapy source, nonstranded, high activity cesium-131, greater than 3.25 mCi, per source.''

Response: Section 1833(t)(2)(H) of the Act requires that we create separate payment groups for brachytherapy sources which reflect the number, isotope, and radioactive intensity of devices of brachytherapy furnished. We have received a recommendation for creation of a new HCPCS code and APC group for a high activity cesium source, and we are currently evaluating whether to establish a new code for a high activity cesium source. Currently, there are two HCPCS codes recognized under the OPPS that describe cesium brachytherapy sources: C2642 (Brachytherapy source, stranded, Cesium-131, per source) and C2643 (Brachytherapy source, non-stranded, Cesium-131, per source). We will continue our established process of implementing new brachytherapy source codes on a quarterly basis as appropriate and providing necessary instruction through quarterly program transmittals.

Consistent with our general practice, we will consider recommendations for new brachytherapy sources during CY 2009, as discussed earlier in this section.

TABLE 33—CURRENT SEPARATELY PAYABLE BRACHYTHERAPY SOURCES FOR CY 2009

CY 2009 HCPCS code	CY 2009 long descriptor	Final CY 2009 APC	Final CY 2009 SI
A9527	Iodine I–125, sodium iodide solution, therapeutic, per millicurie	2632	U
C1716	Brachytherapy source, non-stranded, Gold-198, per source	1716	U
C1717	Brachytherapy source, non-stranded, High Dose Rate Iridium-192, per source.	1717	U
C1719	Brachytherapy source, non-stranded, Non-High Dose Rate Iridium-192, per source.	1719	U
C2616	Brachytherapy source, non-stranded, Yttrium-90, per source	2616	U
C2634	Brachytherapy source, non-stranded, High Activity, Iodine-125, greater than 1.01 mCi (NIST), per source.	2634	U
C2635	Brachytherapy source, non-stranded, High Activity, Palladium-103, greater than 2.2 mCi (NIST), per source.	2635	U
C2636	Brachytherapy linear source, non-stranded, Palladium-103, per 1MM	2636	U
C2638	Brachytherapy source, stranded, Iodine-125, per source	2638	U
C2639	Brachytherapy source, non-stranded, Iodine-125, per source	2639	U
C2640	Brachytherapy source, stranded, Palladium-103, per source	2640	U

TABLE 33—CURRENT SEPARATELY PAYABLE BRACHYTHERAPY SOURCES FOR CY 2009—Continued

CY 2009 HCPCS code	CY 2009 long descriptor	Final CY 2009 APC	Final CY 2009 SI
C2641	Brachytherapy source, non-stranded, Palladium-103, per source	2641	U
C2642	Brachytherapy source, stranded, Cesium-131, per source	2642	U
C2643	Brachytherapy source, non-stranded, Cesium-131, per source	2643	U
C2698	Brachytherapy source, stranded, not otherwise specified, per source	2698	U
C2699	Brachytherapy source, non-stranded, not otherwise specified, per source	2699	U

VIII. OPPS Payment for Drug Administration Services

A. Background

In CY 2005, in response to the recommendations made by commenters and the hospital industry, OPPS transitioned 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 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, incorporating 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 comments on our proposed rule and feedback from the hospital community and the APC Panel, we implemented the full set of CPT codes, including codes incorporating the concepts of initial, sequential, and concurrent. 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.

B. Coding and Payment for Drug Administration Services

As we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41503), the CY 2009 ratesetting process affords us the first opportunity to examine hospital claims data for the full set of CPT codes that reflect the concepts of initial, sequential, and concurrent services. We performed our standard annual OPPS review of the clinical and resource characteristics of the drug administration HCPCS codes assigned to APCs 0436 (Level I Drug Administration), 0437 (Level II Drug Administration), 0438 (Level III Drug Administration), 0439 (Level IV Drug Administration), 0440 (Level V Drug Administration), and 0441 (Level VI Drug Administration) for CY 2008 based on the CY 2007 claims data available for the CY 2009 OPPS/ASC proposed rule. Under the CY 2008 APC configurations for drug administration services, we observed several 2 times violations among the 6 APCs. Therefore, we proposed to reconfigure the drug administration APCs for CY 2009 to improve the clinical and resource homogeneity of the APCs. (We refer readers to sections III.B.2. and 3. of this final rule with comment period for further discussion of the 2 times rule.)

As a result of our hospital cost analysis and detailed clinical review, we proposed 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. These APCs generally demonstrate 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. As indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41503), we do not believe that six drug administration APCs continue to be necessary to pay appropriately for drug administration services based on the significant clinical and resource differences among services. Instead, we believe that the proposed five-level APC structure for CY 2009 is the more appropriate structure based on hospital claims data for the full range of CPT drug administration codes. Our proposed five-level APC structure was originally included as Table 30 of the CY 2009 OPPS/ASC proposed rule and reprinted in replacement Table 30 included in a correction notice published in the **Federal Register** (73 FR 46575) on August 11, 2008, subsequent to the issuance of the CY 2009 OPPS/ASC proposed rule.

As noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41503), we presented a potential four-level drug administration APC structure to the APC Panel during the March 2008 APC Panel meeting. After reviewing the data, the APC Panel recommended that CMS not implement this configuration until more data are available and that CMS provide the APC Panel with a crosswalk analysis of the data. We accepted the APC Panel's recommendation and, therefore, did not propose to implement a four-level APC structure for drug administration services in CY 2009.

Comment: Several commenters supported the continued use of the full range of CPT drug administration codes for billing purposes under the OPPS. Conversely, one commenter requested that CMS return to a coding system that groups hydration services with diagnostic, prophylactic and therapeutic services for the first hour of infusion and additional hours of infusions.

Response: We continue to believe that the use of the full set of drug administration CPT codes allows hospitals to use one set of codes for all

payers, minimizing the administrative burden on hospitals. Hospitals have described to us the challenges associated with maintaining different code sets for different payers, and we do not currently see any reason to change from the use of CPT codes for reporting drug administration services under the CY 2009 OPPS.

Our proposal to move from a six-level APC structure to a five-level structure does not affect hospital billing for drug administration services. We proposed to continue to allow hospitals to use the entire set of drug administration CPT codes for purposes of reporting these services. APC reconfiguration is a regular part of the annual OPPS update in response to our assessment of the most recent hospital claims data. Although changes to the APC assignments of HCPCS codes, including the drug administration CPT codes, affect hospital payment for services, they do not require any coding changes by hospitals.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to continue use of the full range of CPT drug administration codes for the CY 2009 OPPS.

Comment: Several commenters supported the proposal to restructure the drug administration APCs to a five-level APC structure. These commenters expressed appreciation of the proposed increase in payment for certain drug administration services. Furthermore, several commenters expressed appreciation for the timely review and proposed modifications in response to new claims data and indicated their belief that the proposed structure would result in more accurate payment for drug administration services under the OPPS.

Some commenters objected to the proposed five-level APC structure because they believed that it would place an additional burden on hospitals. A few of these commenters asserted that the data used to establish the proposed five-level APC structure for drug administration services as shown in the CY 2009 OPPS/ASC proposed rule were incomplete or inconsistent. These commenters noted that hospitals had difficulty understanding and properly billing for drug administration services using these codes the first year they were introduced under the OPPS. The commenters argued that the data used for the CY 2009 OPPS/ASC final rule with comment period may be suspect because of widespread billing confusion. From their perspective, this confusion, compounded by CMS's failure to clarify the reporting of scenarios such as undocumented infusion stop times and lack of a universal list of drugs that are considered biological response modifiers, led to inconsistent reporting of these drug administration codes across hospitals. The commenters suggested that CMS collect at least 1 additional year of claims data before using this data to inform a restructuring of the drug administration APCs, in order to take into consideration the hospital learning curve that would result, ultimately, in accurate and stable claims data.

In addition, some commenters noted that the CY 2008 CPT hierarchy for reporting drug administration codes used in the facility setting (as included in CPT instructions preceding the Hydration, Therapeutic, Prophylactic, and Diagnostic Injections and Infusions section of CPT codes) was not in place in CY 2007, and because CMS uses CY 2007 hospital claims data to calculate the CY 2009 OPPS payment rates, this hierarchy was not appropriately reflected in the claims data. These commenters were concerned that the new CPT reporting hierarchy altered the billing practices of hospitals significantly so that CMS would eventually see a difference in costs from claims data and, therefore, a transition to a five-level APC structure before these CY 2008 data were available would be premature.

Another commenter also stated that the proposed APCs are inconsistent with CPT coding and medical practice, and that the CPT codes need to be grouped in a way that represents better clinical coherence. Finally, some commenters were concerned that payment for certain drug administration services would decline under the proposed five-level APC structure.

Response: We last reconfigured the drug administration APCs for CY 2007 when we first had 1 year of claims data reflecting the costs of predecessor drug administration CPT codes. Therefore, in parallel fashion we believe it was appropriate to propose to reconfigure the drug administration APCs for CY 2009 when we first have 1 year of hospital claims data for the full range of CPT codes. Our prior assignments of newly recognized CPT codes without historical costs from hospital claims data were based only on estimates of hospital resource costs, and our usual practice is to closely examine the APC assignments of all HCPCS codes once we have actual claims data.

As we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41503), the CY 2009 ratesetting process afforded us the first opportunity to examine hospital claims data for the full set of CPT codes implemented in CY 2007 for the OPPS that reflect the concepts of initial, concurrent, and sequential services. These CPT codes were first available to hospitals in CY 2006; however, because of hospital concerns regarding incorporating these new concepts into their systems, we chose at that time not to implement these codes under the OPPS. This provided hospitals with the opportunity to implement these codes for non-OPPS payers for CY 2006 and gain experience in their reporting, while retaining drug administration billing codes that did not include the concepts of initial, concurrent, and sequential services for OPPS reporting and payment. Therefore, we had no reason to suspect that hospitals would suffer from widespread billing confusion or inconsistent reporting of these drug administration codes across hospitals. Based on comments we received to our CY 2007 OPPS/ASC proposed rule, we believed that hospitals were prepared to fully implement these CPT drug administration codes for the CY 2007 OPPS, complying fully with the descriptors of the CPT codes. As stated in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68116), ''* * * commenters responding to our CY 2007 proposed rule * * * noted that the operational issues were no longer a primary concern with drug administration and coding, and they had gained valuable experience over the past year reporting these codes to non-Medicare payers.''

As we first indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41503), and as we are confirming in this final rule with comment period, for most of the drug administration services, we have thousands of single bills available for ratesetting from the claims submitted by thousands of hospitals, increasing our confidence in the accuracy and stability of the claims data. In addition, our bypass code methodology as described in section II.A.1.b. of this final rule with comment period, which specifically incorporates packaged costs into the costs of the initial drug administration service and not into the additional drug administration services provided in the same hospital encounter, ensures that the single claims used for ratesetting represent a large proportion of total hospital claims for most drug administration services. Therefore, the CY 2007 hospital claims data essentially reflect the second year of hospitals' use of the CPT codes with the concepts of initial, concurrent, and sequential services. Although CY 2007 is only the first year of their use for

OPPS purposes, hospitals had been using these codes for other payers for a full year before they were implemented under the Medicare OPPS. As a result, we have no reason to believe that our data should not be used for ratesetting purposes. In addition, we note that there have been instances in the past for drug administration services where the first year of data was used to establish payment rates once it was available, such as for the additional hour infusion codes. Furthermore, for the above reasons we also believe it is unnecessary to collect an additional year of data before restructuring the drug administration APCs.

While commenters correctly observed that the drug administration hierarchy for services performed in the facility setting was not in place when hospitals implemented the revised CPT codes in CY 2007 and, therefore, is not reflected in our claims data for CY 2009 ratesetting purposes, it is our belief that the hierarchy detailed reporting practices were already commonly being used by the majority of hospitals. We do not believe that the hierarchy implemented in CY 2008 for drug administration services substantially changed hospital billing practices in most cases. For these reasons, we continue to believe that our hospital claims data for drug administration services provided in CY 2007 provide an accurate representation of the costs of these hospital services.

In addition, we believe that our APC groupings are consistent with CPT coding and medical practice because all services assigned to the drug administration APCs are drug administration services. While the specific resources used for different drug administration procedures may vary somewhat from CPT code to CPT code, this variation is not sufficient to warrant additional APCs for essentially similar services.

We have performed our standard review of the costs of drug administration services based on updated data for this final rule with comment period, and we continue to believe that a five-level structure for drug administration services is appropriate for CY 2009. Therefore, as a result of this analysis and for the reasons discussed above, we believe that the proposed five-level drug administration APC structure is the most appropriate after examination of the robust set of drug administration claims available for CY 2009 ratesetting because the proposed structure results in payment groups with greater clinical and resource homogeneity. In addition, we do not believe that a crosswalk analysis of the cost data to the CY 2008 six-level APC structure is pertinent because, for a number of the CPT codes, our APC assignments prior to CY 2009 were based only on our estimates of the expected procedure costs, and not based on hospitals' actual costs for services reported according to the current CPT code descriptors and guidelines.

Comment: A few commenters expressed specific concern that according to the CPT reporting hierarchy implemented for facilities in CY 2008, hospital claims data may not accurately represent the resources required when a hydration service is actually provided as the first service, especially when it is followed by a service, such as an injection of a drug, that would be reported as the initial service according to the CPT hierarchy.

Response: During the development of new drug administration codes implemented by CPT in CY 2006, the AMA, the creators and maintainers of the Level I HCPCS codes (CPT codes), determined that the required resources and clinical characteristics of hydration services and therapeutic, prophylactic, and diagnostic drug administration services were sufficiently distinct to warrant different codes for the first hour of infusion and additional hours of infusion for these two types of services. Further, the AMA implemented a hierarchy for reporting drug administration services in the facility setting where chemotherapy services are primary to therapeutic, prophylactic, and diagnostic services, which are primary to hydration services. In addition, the hierarchy specifies that infusions are considered primary to pushes, which are considered primary to injections. Just as the CPT codes are under the authority of the AMA, so are these instructions that preface the affected CPT codes and, in general, we adopt CPT instructions for reporting services under the OPPS. As discussed earlier, although reporting according to the hierarchy will first be specifically reflected in the CY 2008 OPPS claims data available for the CY 2010 OPPS update, we believe that the hierarchy detailed reporting practices that were already commonly being used by the majority of hospitals. We do not believe that the hierarchy implemented in CY 2008 for drug administration services substantially changed hospital billing practices in most cases, and we believe that our final CY 2009 payment rates for these services is appropriate for drug administration CPT codes reported in accordance with the specified hierarchy for CY 2009.

Comment: One commenter requested that CMS reconsider the proposed APC assignment of CPT code 90765 (Intravenous infusion, for therapy, prophylaxis, or diagnosis, initial, up to one hour), and stated that the CPT code median cost is substantially higher than the median cost of the APC.

Response: For the CY 2009 OPPS/ASC proposed rule, we proposed to assign CPT code 90765 to APC 0439 (Level IV Drug Administration). The proposed code-specific median cost for this service was approximately $127, and the proposed median cost for APC 0439 was also approximately $127. According to our standard practice, we reevaluate proposed HCPCS code assignments between the proposed and final rules after updating our data, as discussed in section II.A. of this final rule with comment period. For this final rule with comment period, the updated final median cost of CPT code 90765 of approximately $126 is the same as the APC median cost of approximately $126, and we believe that this is the most appropriate APC assignment for this drug administration code.

Comment: One commenter stated that, under the proposed five-level APC structure, a 2 times rule violation appears in APC 0436 (Level I Drug Administration). The commenter noted that the proposed median cost for CPT code 90779 (Unlisted therapeutic, prophylactic or diagnostic intravenous or intra-arterial injection or infusion) was approximately $77, while the proposed median cost for APC 0436 was approximately $25. The commenter suggested reassigning CPT code 90779 to APC 0438 (Level III Drug Administration), with a proposed median cost of approximately $74.

Response: As a matter of established OPPS policy described in the CY 2005 OPPS final rule with comment period (69 FR 65724 through 65725), we assign all unlisted HCPCS codes, such as CPT code 90779, to the lowest level APC within the appropriate clinical series. By definition, ''unlisted'' or ''not otherwise classified'' codes do not describe the services being performed, and the services coded using ''unlisted'' codes vary over time as new CPT and HCPCS codes are developed. Therefore, it is impossible for any level of analysis of past hospital data to result in appropriate placement of the service for the upcoming year in an APC in which there is clinical integrity of the groups and weights. Therefore, we continue to believe that the appropriate default, in the absence of a code that describes the service being furnished, is placement in the lowest level APC within the clinical category in which the unlisted code falls. The assignment of the unlisted codes to the lowest level APC in the

clinical category specified in the code provides a reasonable means for interim payment until such time as there is a code that specifically describes what is being paid. It encourages the creation of codes where appropriate and mitigates against overpayment of services that are not clearly identified on the bill. Our assignment of CPT code 90779 to APC 0436 is consistent with this policy. The hospital cost data for unlisted HCPCS codes, including CPT code 90779, are not used for ratesetting and, furthermore, the costs of unlisted HCPCS codes are not subject to the 2 times rule. For additional information on the 2 times rule, we refer readers to sections III.B.2 and 3 of this final rule with comment period.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to implement a five-level APC structure for drug administration services, with final assignment of all HCPCS codes as proposed. Table 34 below displays the five finalized APC groups for drug administration services for CY 2009. We note that several of the CY 2008 CPT codes for drug administration services have been renumbered for CY 2009. We provide both the CY 2008 CPT codes and the CY 2009 CPT codes, along with the CY 2009 long code descriptors, in Table 34 below.

Comment: Several commenters requested that CMS reconsider the proposed packaged status of CPT code 90768 (Intravenous infusion, for therapy, prophylaxis, or diagnosis; concurrent infusion). The commenters noted that the service described by this code, for which hospital claims data are first available in CY 2007, requires additional facility resources. They believed that because CMS now has claims data upon which to set a specific payment rate for the service, the OPPS should pay separately for CPT code 90768 in CY 2009.

Response: We agree with commenters that this code was first introduced in CY 2007 under the OPPS and that we have cost data for this CPT code based on historical hospital claims data. However, we believe that this code remains appropriate for packaging. As we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66787 through 66788), in deciding 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; 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. CPT code 90768, by definition, is always provided in association with other intravenous infusions, and we continue to believe that it is most appropriately packaged under the OPPS. Furthermore, to reduce the size of the APC payment groups and establish separate payment for this currently packaged ancillary and supportive service would be inconsistent with our overall strategy to encourage hospitals to use resources more efficiently by increasing the size of the OPPS payment bundles.

After consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to package payment for CPT code 90768 for CY 2009.

TABLE 34—CY 2009 DRUG ADMINISTRATION APCS

Final CY 2009 APC	Final CY 2009 approximate APC median cost	CY 2008 HCPCS code	CY 2009 HCPCS code	CY 2009 long descriptor
0436	$24	90471	90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine/toxoid).
		90472	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	90473	Immunization administration by intranasal or oral route; one vaccine (single or combination vaccine/toxoid).
		90474	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).
		90761	96361	Intravenous infusion, hydration; each additional hour (List separately in addition to code for primary procedure).
		90766	96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure).
		90771	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).
		90772	96372	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular.
		90779	96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion.
		95115	95115	Professional services for allergen immunotherapy not including provision of allergenic extracts; single injection.
		95117	95117	Professional services for allergen immunotherapy not including provision of allergenic extracts; two or more injections.
		95145	95145	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); single stinging insect venom.
		95165	95165	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses).

TABLE 34—CY 2009 DRUG ADMINISTRATION APCS—Continued

Final CY 2009 APC	Final CY 2009 approximate APC median cost	CY 2008 HCPCS code	CY 2009 HCPCS code	CY 2009 long descriptor
		95170	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).
		96549	96549	Unlisted chemotherapy procedure.
0437	$35	90767	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).
		90770	96370	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure).
		90773	96373	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intra-arterial.
		90774	96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug.
		90775	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).
		95144	95144	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single dose vial(s) (specify number of vials).
		95148	95148	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); four single stinging insect venoms.
		96401	96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic.
		96402	96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic.
		96405	96405	Chemotherapy administration; intralesional, up to and including 7 lesions.
		96415	96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure).
0438	$72	90760	96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour.
		90769	96369	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to one hour, including pump set-up and establishment of subcutaneous infusion site(s).
		95146	95146	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 2 single stinging insect venoms.
		95147	95147	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 3 single stinging insect venoms.
		96406	96406	Chemotherapy administration; intralesional, more than 7 lesions.
		96411	96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug (List separately in addition to code for primary procedure).
		96417	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).
		96423	96423	Chemotherapy administration, intra-arterial; infusion technique, each additional hour (List separately in addition to code for primary procedure).
0439	$126	90765	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour.
		95149	95149	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 5 single stinging insect venoms.
		96409	96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug.
		96420	96420	Chemotherapy administration, intra-arterial; push technique.
		96522	96522	Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (e.g., intravenous, intra-arterial).
		96542	96542	Chemotherapy injection, subarachnoid or intraventricular via subcutaneous reservoir, single or multiple agents.
0440	$184	95990	95990	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular).
		95991	95991	Refilling and maintenance of implantable pump or reservoir for drug delivery, spinal (intrathecal, epidural) or brain (intraventricular); administered by physician.
		96413	96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.

TABLE 34—CY 2009 DRUG ADMINISTRATION APCS—Continued

Final CY 2009 APC	Final CY 2009 approximate APC median cost	CY 2008 HCPCS code	CY 2009 HCPCS code	CY 2009 long descriptor
		96416	96416	Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump.
		96422	96422	Chemotherapy administration, intra-arterial; infusion technique, up to 1 hour.
		96425	96425	Chemotherapy administration, intra-arterial; infusion technique, initiation of prolonged infusion (more than 8 hours), requiring the use of a portable or implantable pump.
		96440	96440	Chemotherapy administration into pleural cavity, requiring and including thoracentesis.
		96445	96445	Chemotherapy administration into peritoneal cavity, requiring and including peritoneocentesis.
		96450	96450	Chemotherapy administration, into CNS (e.g., intrathecal), requiring and including spinal puncture.
		96521	96521	Refilling and maintenance of portable pump.
		C8957	C8957	Intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than eight hours), requiring use of portable or implantable pump.

IX. 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. CPT indicates that office or other outpatient visit codes are used to report evaluation and management (E/M) services provided in the physician's office or in an outpatient or other ambulatory facility. For OPPS purposes, we refer to these as clinic visit codes. CPT also indicates that emergency department visit codes are used to report E/M services provided in the emergency department, which is defined as an ''organized hospital-based facility for the provision of unscheduled episodic services to patients who present for immediate medical attention. The facility must be available 24 hours a day.'' For OPPS purposes, we refer to these as emergency department visit codes that specifically apply to the reporting of visits to Type A emergency departments. Furthermore, for CY 2007 we established five new Level II HCPCS codes to report visits to Type B emergency departments (defined as dedicated emergency departments that incur Emergency Medical Treatment and Labor Act (EMTALA) of 1986 (Pub. L. 99–272) obligations but that do not meet the Type A emergency department definition, as described in more detail below). These new Level II HCPCS codes were developed because there were no CPT codes at that time that fully described services provided in this type of facility. CPT defines critical care services to be reported with critical care CPT codes as the ''direct delivery by a physician(s) of medical care for a critically ill or critically injured patient.'' Under the OPPS, in Transmittal 1139, Change Request 5438, dated December 22, 2006, we stated that 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. We also established HCPCS code G0390 (Trauma response team associated with hospital critical care service) in CY 2007 for the reporting of a trauma response in association with critical care services. We refer readers to section III.D.7.f. of this final rule with comment period for further discussion of payment for a trauma response associated with hospital critical care services.

Currently, CMS instructs hospitals to report the CY 2008 CPT codes that describe new and established clinic visits, Type A emergency department visits, and critical care services, and the six Level II HCPCS codes to report Type B emergency department visits and trauma activation provided in association with critical care services. These codes are listed below in Table 35. As we stated in the proposed rule (73 FR 41506), we are not changing the visit HCPCS codes that hospitals report for CY 2009.

TABLE 35—CY 2009 CPT E/M AND LEVEL II HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES

CY 2009 HCPCS code	CY 2009 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).

TABLE 35—CY 2009 CPT E/M AND LEVEL II HCPCS CODES USED TO REPORT CLINIC AND EMERGENCY DEPARTMENT VISITS AND CRITICAL CARE SERVICES—Continued

CY 2009 HCPCS code	CY 2009 descriptor
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.

The majority of CPT code descriptors are applicable to both physician and facility resources associated with specific services. However, we have acknowledged from the beginning of the OPPS that we believe that CPT E/M codes were defined to reflect the activities of physicians and do not necessarily fully describe the range and mix of services provided by hospitals during visits of clinic or emergency department patients or critical care encounters. While awaiting the development of a national set of facility-specific codes and guidelines, 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.

During its March 2008 APC Panel meeting, the APC Panel recommended that CMS provide, for review by the Visits and Observation Subcommittee at the next CY 2008 APC Panel meeting: (1) Frequency and median cost data on new and established patient clinic visits and Type A and Type B emergency department visits; (2) data on CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) and APC 617 (Critical Care); and (3) frequency and median cost data on the extended assessment and management composite APCs (that is, APCs 8002 and 8003). We adopted all three of these recommendations and provided frequency and cost data related to these services at the August 2008 APC Panel meeting. During its August 2008 meeting, the APC Panel requested, for review by the APC Panel at the next CY 2009 APC Panel meeting, an analysis of CY 2008 claims data for clinic visits, Type A and Type B emergency department visits, and extended assessment and management composite APCs. The APC Panel also recommended that the work of the Visits and Observation Subcommittee continue. We are adopting these recommendations.

The complete discussion related to visits is provided below. A complete discussion related to the extended assessment and management composite APCs can be found in section II.A.2.e.(1) of this final rule with comment period.

B. Policies for Hospital Outpatient Visits

1. Clinic Visits: New and Established Patient Visits

CPT defines an established patient as ''one who has received professional services from the physician or another physician of the same specialty who belongs to the same group practice, within the past 3 years.'' To apply this definition to hospital clinic visits, we stated in the April 7, 2000 OPPS final rule with comment period (65 FR 18451), that the meanings of ''new'' and ''established'' pertain to whether or not the patient already has a hospital medical record number. If the patient has a hospital medical record that was created within the past 3 years, that patient is considered an established patient to the hospital. The same patient could be ''new'' to the physician but an ''established'' patient to the hospital. The opposite could be true if the physician has a longstanding relationship with the patient, in which case the patient would be an ''established'' patient with respect to the physician and a ''new'' patient with respect to the hospital. Our resource cost data continue to show that new patient visits are consistently more costly than established patient visits of the same level.

Since the implementation of the OPPS, we have received very few comments related to the definitions of new and established patient visits. However, during the past year, we have heard from several provider groups that hospitals cannot easily distinguish between new and established patients for purposes of correctly reporting clinic visits under the OPPS, based on the definition above. We considered several options for refining the definitions of new and established patients as they would apply under the CY 2009 OPPS in order to reduce hospitals' administrative burden associated with reporting appropriate clinic visit CPT codes.

We considered proposing to eliminate the distinction between new and established patient visits under the OPPS, as had previously been recommended by the APC Panel for CY 2008. We considered instructing hospitals to bill all visits as established patient visits and the hospital would determine the appropriate code level based on the resources expended during the visit. However, because hospital claims data continue to show significant cost differences between new and established patient visits, we believe it is most appropriate to continue to recognize the CPT codes for both new

and established patient visits and, in some cases, provide differential payment for new and established patient visits of the same level. In addition, we continue to believe it is important that CPT codes be reported consistent with their code descriptors, and that some patients will always be new to the hospital, regardless of any potential refinement in the definition of ''new'' for reporting clinical visits under the OPPS. Therefore, as we stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41507), we did not propose this approach for reporting CPT codes for clinic visits for CY 2009.

Another alternative we considered was proposing to define an established patient as a patient who already had a hospital medical record number at the hospital where he or she was currently receiving services, regardless of when this medical record was created. Several commenters to the CY 2008 OPPS/ASC proposed rule preferred this distinction rather than the current policy, which requires hospitals to determine if the patient's hospital medical record was created within the past 3 years (72 FR 66793). However, one commenter noted an extreme example in which a patient who was born at a hospital and assigned a medical record number would always be considered an established patient to that hospital, even if the patient was not treated again at that hospital until decades later. We continue to believe it is appropriate to include a time limit when determining whether a patient is new or established from the hospital's perspective because we would expect that care of a patient who was not treated at the hospital for several years prior to a visit could require significantly greater hospital resources than care for a patient who was recently treated at the hospital. Therefore, as we stated in the proposed rule (73 FR 41507), we did not propose this alternative for CY 2009.

We considered proposing to modify the new and established patient definitions for reporting clinic visits under the OPPS so they would pertain to whether or not the patient was registered in a specific hospital clinic within the past 3 years. However, we believe this approach could be problematic because we do not believe that every clinic has clear administrative boundaries that define whether the patient was previously seen in that particular clinic. For example, a hospital-based clinic may have several locations, including on-campus and off-campus sites, or a specific area of the hospital may house two or more specialty clinics that treat disparate types of clinical conditions.

We considered the options described above but did not propose to adopt these three alternatives for CY 2009. Instead, we proposed to modify the definitions of ''new'' and ''established'' patients as they apply to hospital outpatient visits. Specifically, the meanings of ''new'' and ''established'' patients would pertain to whether or not the patient has been registered as an inpatient or outpatient of the hospital within the past 3 years. Under this proposed modification, hospitals would not need to determine the specific clinic where the patient was previously treated because the modified definition would not rely upon when the medical record was initially created but rather would depend upon whether the individual has been registered as a hospital inpatient or outpatient within the previous 3 years.

In addition, hospitals would also not need to determine when the medical record was initially created. If the patient has been registered as an inpatient or outpatient of the hospital within the past 3 years, that patient is considered an ''established'' patient to the hospital. If a patient has been registered as an outpatient in a hospital's off-campus provider-based clinic or emergency department within the past 3 years, that patient would still be considered an ''established'' patient to the hospital for an on-campus or off-campus clinic visit even if the medical record was initially created by the hospital prior to the past 3 years. Consistent with past policy, the same patient may be ''new'' to the physician but an ''established'' patient to the hospital. The opposite would be true if the physician has a longstanding relationship with the patient, in which case the patient would be an ''established'' patient with respect to the physician and a ''new'' patient with respect to the hospital. We believe that our proposed modified definition of new and established patients for reporting visits under the OPPS would be administratively straightforward for hospitals to apply, while continuing to capture differences in hospital resources required to provide new and established patient clinic visits. Furthermore, we believe that costs from historical hospital claims data for services reported under the past OPPS interpretation of new and established patient visits could simply be crosswalked to the expected costs of the corresponding visit level reported under our proposed modified definition, thereby providing appropriate payment for new and established clinic visits for all five levels until CY 2009 claims data reflecting the refined definitions would be available for CY 2011 ratesetting. We expect only minimal cost differences for clinic visits based on these proposed new definitions established for CY 2009. We invited the public to specifically comment on the proposed modified definitions of new and established patients under the OPPS.

Comment: Most commenters supported the first alternative described above and requested that CMS eliminate the need for hospitals to distinguish between new and established patient visits because of the administrative difficulty in determining the correct visit type. Specifically, these commenters suggested that hospitals bill an appropriate visit code, based on the resources expended in the visit at a level determined by the hospitals' internal reporting guidelines, without distinguishing whether the patient is new or established. Several commenters requested that we adopt the APC Panel's March 2007 recommendation, as related to visits. Specifically, the APC Panel recommended at that time that CMS eliminate the ''new'' and ''established'' patient distinctions in the reporting of hospital clinic visits. During its discussion, the APC Panel suggested that hospitals bill the appropriate level clinic visit code according to the resources expended while treating the beneficiary, based on each hospital's internal guidelines. The APC Panel also suggested that each hospital's internal guidelines reflect resource cost differences (if a difference exists) between new and established patients.

Several commenters suggested that CMS change the status of the new patient visit CPT codes to nonpayable and require hospitals to bill the established patient visit codes exclusively. One commenter acknowledged the payment difference between new and established patient visits but noted that its hospital system chose to bill all visits as established patients because of the administrative burden associated with determining whether a patient is new or established. Other commenters suggested that CMS require hospitals to bill the new patient visit codes exclusively, particularly in urgent care clinics, claiming that the patients' previous encounters are rarely relevant to future visits. Another commenter noted that resource efficiencies that exist when treating an established patient do not pertain in the HOPD in the same way as they apply to the physician's office.

If CMS were to finalize a policy that required hospitals to bill only one type of visit code for a given visit level, several commenters suggested setting

the payment rate for the reportable visit code at a blend of the new and established patient visit rates for that level. Several commenters believed that, under both the current and proposed definitions for new and established patients, it is difficult for mid-sized hospitals and impossible for small hospitals to determine whether a patient visit should be reported with the new or established patient visit code. Many commenters suggested that the AMA create hospital-specific Category I CPT visit codes that do not distinguish between new and established patient visits, as appropriate for reporting hospital resource use. These commenters indicated that it would be most appropriate for the AMA to create these hospital-specific visit codes following implementation of national visit guidelines. Other commenters requested the creation of Level II HCPCS G-codes for reporting clinic visits, noting that implementation of national guidelines does not appear to be imminent, and that HCPCS G-codes would solve the immediate problem.

While most commenters recommended that CMS eliminate the distinction between new and established patient visits, other commenters supported the proposed definitions for new and established patients. Some commenters supported the general proposal to refine the definition of a new patient under the OPPS, but suggested that the 3 year window was too long because significant changes can occur in a patient's medical history that would not be reflected in a medical record that had not been updated for 3 years. Other commenters noted a preference for reporting visits without distinguishing between new and established patient visits, but stated that if it was necessary to distinguish between new and established patient visits, the proposed refinement to the definition of a new patient was an improvement from the previous definition.

One commenter suggested that CMS finalize another one of the alternatives discussed above and modify the new and established patient definitions for reporting clinic visits under the OPPS so they would pertain to whether or not the patient was registered in a specific hospital clinic within the past 3 years.

Response: Because hospitals will be reporting CPT codes for CY 2009 and we continue to observe significant cost differences between new and established patient visits of the same level, we will continue to recognize new and established patient visit codes under the CY 2009 OPPS, consistent with their CPT code descriptors. We agree with the commenters that it could be less burdensome from a coding perspective if hospitals only needed to report one set of codes, rather than continuing to distinguish between new and established patient visits. However, we do not believe that this would pay most appropriately and accurately for new and established visits at all five levels based on the costs that have been reported to us by hospitals for these services. For CY 2009, hospitals should continue to distinguish between new and established patient visits, consistent with their CPT code descriptors, in order to receive appropriate payment for these services and so that accurate claims data are available for future OPPS ratesetting. While we acknowledge that some hospitals may prefer HCPCS G-codes rather than continuing to distinguish between new and established patient visits in reporting CPT codes, we are reluctant to again consider establishing HCPCS G-codes, particularly in the absence of national guidelines, based on past comments we have received to prior proposed rules. Furthermore, public comments we have received to the CY 2009 OPPS/ASC proposed rule and prior proposed rules on the establishment of Level II HCPCS codes for services other than visits generally have reflected a strong general preference on the part of commenters for OPPS' use of CPT codes rather than Level II HCPCS codes.

The majority of commenters who expressed an opinion about the definitions of new and established patients, if we were to continue to recognize a distinction, believed that the proposed new and established patient definitions would be easier to apply than the current definitions. While we are continuing to recognize the CPT codes for new and established patient visits, we are interested in minimizing the administrative reporting burden of hospitals, while continuing to capture resource differences between new and established patient visits of the same level. Therefore, we believe that adopting our proposed modifications to these definitions is the most desirable approach for CY 2009.

Comment: One commenter asked whether the new and established patient definitions apply to CPT codes other than CPT codes 99201 through 99205 and CPT codes 99211 through 99215. Specifically, the commenter questioned whether the definitions would apply to CPT codes 99605 (Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, new patient) and 99606 (Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, established patient).

Response: CPT codes 99605 and 99606 are assigned status indicator ''E'' under the OPPS, indicating that they are not payable under the OPPS and should not be reported on OPPS claims. If a hospital provided medication therapy management services described by the CPT codes as part of a clinic visit, emergency department visit, or a procedure, that visit or procedure would be reportable, and the medication therapy management services provided as part of that service would be covered by Medicare, but would not be separately payable. For a complete discussion of these codes, we refer readers to the CY 2007 OPPS/ASC final rule with comment period (71 FR 68061). The discussion relates to CPT codes 0115T through 0117T, which were the predecessor codes to CPT codes 99605 through 99607.

In general, however, the new and established patient definitions for CY 2009 would also apply under the OPPS to payable CPT codes other than CPT codes 99201 through 99205 and 99211 through 99215 that distinguish between new and established patients unless we have specifically provided different instructions regarding the reporting of those codes.

After consideration of the public comments received, and for the reasons explained in this section, we are finalizing our CY 2009 proposal, without modification, to change the definitions of new and established patients as they relate to reporting hospital outpatient visits under the OPPS. Specifically, beginning in CY 2009, the meanings of ''new'' and ''established'' patients pertain to 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 the 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 the visit would be considered to be a new patient for that visit.

As discussed further in section II.A.2.e.(1) of this final rule with comment period and consistent with our CY 2008 policy, when calculating the median costs for the clinic visit APCs (0604 through 0608), we will

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 believe that this approach will result in the most accurate cost estimates for APCs 0604 through 0608 for CY 2009.

2. Emergency Department Visits

As described in section IX.A. of this final rule with comment period, CPT defines an emergency department as ''an organized hospital-based facility for the provision of unscheduled episodic services to patients who present for immediate medical attention. The facility must be available 24 hours a day.'' Prior to CY 2007, under the OPPS we restricted the billing of emergency department CPT codes to services furnished at facilities that met this CPT definition. Facilities open less than 24 hours a day should not have reported the emergency department CPT codes for visits.

Sections 1866(a)(1)(I), 1866(a)(1)(N), and 1867 of the Act impose specific obligations on Medicare-participating hospitals and CAHs that offer emergency services. These obligations concern individuals who come to a hospital's dedicated emergency department and request examination or treatment for medical conditions, and apply to all of these individuals, regardless of whether or not they are beneficiaries of any program under the Act. Section 1867(h) of the Act specifically prohibits a delay in providing required screening or stabilization services in order to inquire about the individual's payment method or insurance status. Section 1867(d) of the Act provides for the imposition of civil monetary penalties on hospitals and physicians responsible for failing to meet the provisions listed above. These provisions, taken together, are frequently referred to as the EMTALA provisions.

Section 489.24 of the EMTALA regulations defines ''dedicated emergency department'' as any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements: (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department; (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; or (3) During the calendar year immediately preceding the calendar year in which a determination under the regulations is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

In the CY 2008 OPPS/ASC proposed rule (72 FR 42756), we reiterated our belief that every emergency department that meets the CPT definition of emergency department also qualifies as a dedicated emergency department under EMTALA. However, we indicated that we were aware that there are some departments or facilities of hospitals that meet the definition of a dedicated emergency department under the EMTALA regulations, but that do not meet the more restrictive CPT definition of an emergency department. For example, a hospital department or facility that meets the definition of a dedicated emergency department may not be available 24 hours a day, 7 days a week. Nevertheless, hospitals with such departments or facilities incur EMTALA obligations with respect to an individual who presents to the department and requests, or has requested on his or her behalf, examination or treatment for an emergency medical condition. However, because they did not meet the CPT requirements for reporting emergency visit E/M codes, prior to CY 2007, these facilities were required to bill clinic visit codes for the services they furnished under the OPPS. We had no way to distinguish in our hospital claims data the costs of visits provided in dedicated emergency departments that did not meet the CPT definition of emergency department from the costs of clinic visits.

Prior to CY 2007, some hospitals requested that they be permitted to bill emergency department visit codes under the OPPS for services furnished in a facility that met the CPT definition for reporting emergency department visit E/M codes, except that the facility was not available 24 hours a day. These hospitals believed that their resource costs for visits were more similar to those of emergency departments that met the CPT definition than they were to the resource costs of clinics. Representatives of such facilities argued that emergency department visit payments would be more appropriate, on the grounds that their facilities treated patients with emergency conditions whose costs exceeded the resources reflected in the clinic visit APC payments, even though these emergency departments were not available 24 hours per day. In addition, these hospital representatives indicated that their facilities had EMTALA obligations and should, therefore, be able to receive emergency department visit payments. While these emergency departments may have provided a broader range and intensity of hospital services, and required significant resources to assure their availability and capabilities in comparison with typical hospital outpatient clinics, the fact that they did not operate with all capabilities full-time suggested that hospital resources associated with visits to emergency departments or facilities available less than 24 hours a day might not be as great as the resources associated with emergency departments or facilities that were available 24 hours a day, and that fully met the CPT definition.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68132), we finalized the definition of Type A emergency departments to distinguish them from Type B emergency departments. 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, 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 the five newly created Emergency Visit APCs, specifically 0609 (Level 1 Emergency Visits), 0613 (Level 2 Emergency Visits), 0614 (Level 3 Emergency Visits), 0615 (Level 4 Emergency Visits), and 0616 (Level 5 Emergency Visits).

We defined a Type B emergency department as any dedicated emergency department that incurred EMTALA obligations under § 489.24 of the EMTALA regulations but that did not meet the Type A emergency department definition. 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 in § 489.24, 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. For CYs 2007 and 2008, we assigned the five new Type B emergency department visit codes for services provided in a Type B emergency department to the five Clinic Visit APCs, specifically 0604 (Level 1 Hospital Clinic Visits), 0605 (Level 2 Hospital Clinic Visits), 0606 (Level 3 Hospital Clinic Visits), 0607 (Level 4 Hospital Clinic Visits), and 0608 (Level 5 Hospital Clinic Visits). This payment policy for Type B emergency department visits was similar to our previous policy, which required that services furnished in emergency departments that had an EMTALA obligation but did not meet the CPT definition of emergency department be reported using CPT clinic visit E/M codes, resulting in payments based upon clinic visit APCs. While maintaining the same payment policy for Type B emergency department visits in CYs 2007 and 2008, we believe 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. We noted that the OPPS rulemaking cycle for CY 2009 would be the first year that we would have cost data for these new Type B emergency department HCPCS codes available for analysis.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41509), we summarized the CY 2007 proposed rule cost data available for the CY 2009 ratesetting for the Type B emergency department HCPCS codes G0380 through G0384. Based on those data, 342 hospitals billed at least one Type B emergency department visit code in CY 2007, with a total frequency of visits provided in Type B emergency departments of approximately 200,000. All except 2 of the 342 hospitals reporting Type B emergency department visits in CY 2007 also reported Type A emergency department visits. Overall, many more hospitals (approximately 2,911 total hospitals) reported Type A emergency department visits than Type B emergency department visits. For comparison purposes, the total frequency of visits provided in hospital outpatient clinics and Type A emergency departments is approximately 14.5 million and 10.3 million, respectively.

As stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41509), we performed additional data analyses to gather more information to support our proposal for payment of Type B emergency department visits. This included studying the emergency department visit charges and costs of hospitals that billed Type B emergency department visits, analyzing the cost data for various subsets of hospitals that billed the Type B emergency department visit codes, and comparing visit cost data for hospitals that did and did not bill Type B emergency department visit codes. Hospitals that reported both Type A and Type B emergency department visits billed lower charges for Type B emergency department visits than Type A emergency department visits, presumably reflecting the lower costs for Type B emergency department visits. Moreover, hospitals that billed both Type A and Type B emergency department visits also had lower costs for Type B emergency department visits than Type A emergency department visits at all levels except for the level 5 Type B emergency department visit. The Type A emergency department visit costs for hospitals that billed both Type A and Type B emergency department visits resembled the Type A emergency department visit costs of hospitals that billed only Type A emergency department visits and did not bill any Type B emergency department visits. We also determined that the majority of Type B emergency department visits were reported under an emergency department revenue code. In summary, our further analyses 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, and that the observed differences were not attributable to provider-level differences in the visit costs of the different groups of hospitals reporting Type A and Type B emergency department visits. In other words, the median costs from CY 2007 hospital claims represent real differences in the hospital resource costs for the same level of visit in a Type A or Type B emergency department. As noted earlier in this section, the CY 2007 claims data are the first year of claims data that include providers' cost data for the Type B emergency department visits. We indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41509) that we would continue to perform additional analyses to monitor patterns of billing and costs of these services as additional cost data become available.

We shared preliminary cost and frequency data with the Visits and Observation Subcommittee of the APC Panel and the full APC Panel during its March 2008 meeting. The APC Panel recommended that CMS continue to pay levels 1, 2, and 3 Type B emergency department visits at the corresponding clinic visit levels. The APC Panel also recommended that CMS consider using the clinic visit level 5 APC as the basis of payment for the level 4 Type B emergency department visit and the level 5 Type A emergency department visit APC as the basis of payment for the level 5 Type B emergency department visit. Given the limited data presently available for Type B emergency department visits, the APC Panel also recommended that CMS reconsider payment adjustments as more claims data become available. In general, the APC Panel's recommended configuration would pay appropriately for each level of the Type B emergency department visits, based on the resource costs of the Type B emergency department visits that are reflected in claims data.

In accordance with the APC Panel's assessment, we proposed to establish the payment for Type B emergency department visits in CY 2009 consistent with their median costs, although our proposal did not fully adopt the APC Panel's recommended payment configuration. Specifically, we proposed to establish payment for levels 1, 2, 3, and 4 Type B emergency department visits through four levels of newly created APCs, 0626 (Level 1 Type B Emergency Visits), 0627 (Level 2 Type B Emergency Visits), 0628 (Level 3 Type B Emergency Visits), and 0629 (Level 4 Type B Emergency Visits). In addition, for CY 2009, we proposed to assign HCPCS codes G0380, G0381, G0382, and G0383, the levels 1, 2, 3, and 4 Type B emergency department visit Level II HCPCS codes, to APCs 0626, 0627, 0628, and 0629, respectively. These HCPCS codes would be the only HCPCS codes assigned to these newly created APCs. Furthermore, to distinguish these new APCs from the APCs for levels 1,

2, 3, and 4 Type A emergency department visits, we proposed to modify the titles of the current APCs for these visits to incorporate Type A in their names. We proposed the following titles: APC 0609 (Level 1 Type A Emergency Visits); APC 0613 (Level 2 Type A Emergency Visits); APC 0614 (Level 3 Type A Emergency Visits); and APC 0615 (Level 4 Type A Emergency Visits). Finally, we proposed to map the level 5 Type B emergency department visit code, HCPCS code G0384, to APC 0616 (Level 5 Emergency Visits), which is the same APC that contains CPT code 99285, the level 5 Type A emergency department visit code. Consistent with the APC Panel recommendation, the level 5 Type B emergency department visit payment rate would be the same as the level 5 Type A emergency department visit payment rate based upon the similar median costs for these visits. For this highest level of emergency department visits, the costs of these relatively uncommon visits to Type A and Type B emergency departments are comparable, reflecting the considerable hospital resources required to care for these sick patients in both settings.

During its August 2008 meeting, the APC Panel recommended that CMS adopt the proposed APC assignments and payment rates for Type A and Type B emergency department visits for CY 2009.

The median costs using final rule data for the Type B emergency department visit HCPCS codes, as compared to the clinic visit and Type A emergency visit APC median costs, are shown in Table 36 below.

TABLE 36—COMPARISON OF MEDIAN COSTS FOR CLINIC VISIT APCS, TYPE B EMERGENCY DEPARTMENT VISIT HCPCS CODES, AND TYPE A EMERGENCY VISIT APCS

Visit level	Final CY 2009 clinic visit APC median cost	Final CY 2009 type B emergency department visit HCPCS code-specific median cost	Final CY 2009 type A emergency visit APC median cost
Level 1	$53	$44	$51
Level 2	67	60	84
Level 3	88	87	134
Level 4	111	156	213
Level 5	158	313	317

The median costs of the lowest level visit are similar across all settings, including clinic and Type A and B emergency departments. Visit levels 2 and 3 share similar resource costs in the clinic and Type B emergency department settings, while visits provided in Type A emergency departments have higher estimated resource costs at these levels. The level 4 clinic visit APC is less resource intensive than the level 4 Type B emergency department visit, which is similarly less resource intensive than the level 4 Type A emergency department visit. The Type A and B emergency department level 5 visit median costs are similar to each other and significantly exceed the level 5 clinic visit cost.

Table 37 below displays the APC median costs for each level of Type B emergency department visits using CY 2007 final rule data, under our proposed CY 2009 configuration.

TABLE 37—CY 2009 TYPE B EMERGENCY DEPARTMENT VISIT APC ASSIGNMENTS AND MEDIAN COSTS

Type B emergency department visit level	Final CY 2009 APC assignment	Final CY 2009 APC median cost
Level 1	0626	$44
Level 2	0627	60
Level 3	0628	87
Level 4	0629	156
Level 5	0616	317

For the CY 2009 OPPS, we also proposed to include HCPCS code G0384 in the criteria that determine eligibility for payment of composite APC 8003 (Level II Extended Assessment and Management Composite).

Comment: The commenters overwhelmingly supported the payment proposal related to Type B emergency department visits. One commenter specifically commended CMS for systematically creating HCPCS codes for Type B emergency department visits with the specific goal of measuring resource cost data to determine appropriate payment rates. While most commenters believed it was appropriate to assign HCPCS code G0384 (Level 5 Type B emergency visit) to APC 0616 (Level 5 Emergency Visit), thereby paying the level 5 Type B emergency department visit at the same rate as the level 5 Type A emergency department visit, several commenters requested that CMS assign HCPCS code G0384 to its own Type B emergency department APC. Other commenters requested that CMS instruct hospitals to set charges that specifically reflect resource use for Type B emergency department visits, whether provided in a separate area of the hospital, at an off-site location, or in a ''carved-out'' section of the main emergency department. Some commenters noted their surprise that hours of operation would lead to cost differences between Type A and Type B emergency department visits at most levels, particularly because level 5 emergency department visits in both Type A and Type B emergency departments have similar costs. One

commenter suggested that CMS should determine the true cause of cost differences between Type A and Type B emergency department visits. Many commenters recommended that CMS continue to monitor data and propose future payment changes as necessary. One commenter hypothesized that Type B emergency department visit costs would grow more similar to Type A emergency department visit costs than clinic visit costs over time. Another commenter noted that hospitals are still becoming familiar with the relatively new Type B emergency department visit HCPCS codes so CMS should perform similar analyses next year, using an additional year of data.

Response: We agree with the commenters that it would be appropriate and informative to update our analyses of the cost data related to Type A and Type B emergency department visits in preparation for the CY 2010 rulemaking, and periodically thereafter, to determine whether a modified APC configuration would be appropriate. This is, in fact, our regular practice in the course of the annual rulemaking cycle for all OPPS services. In addition, we will specifically analyze the Type B emergency department visit level distributions when an additional year of data are available, and regularly thereafter. We do not expect to see significant increases in the proportion of high level Type B emergency department visits as a result of the final CY 2009 payment policy for these visits, which pays more for these visits in CY 2009 than in CY 2008.

For CY 2009, we do not believe it is necessary to assign HCPCS code G0384 (Level 5 Type B emergency visit) to its own APC rather than assigning it to APC 0616 with the level 5 Type A emergency visit CPT code as proposed. For this highest level of emergency department visits, the costs of these relatively uncommon visits to Type A and Type B emergency departments are comparable, reflecting the considerable hospital resources required to care for these sick patients in both settings. We also believe that level 5 emergency department visits to Type A and Type B emergency departments are clinically similar as well, so that the two HCPCS codes are most appropriately assigned to the same clinical APC. As always, we encourage hospitals to set charges that specifically reflect resource use for all services provided, including Type A and Type B emergency department visits.

We continue to believe that an emergency department's hours of operation and associated available capacity contribute significantly to the cost differences between levels 1 through 4 Type A and Type B emergency department visits. We acknowledge that the costs of the level 5 emergency department visits in both the Type A and Type B emergency department settings are comparable, and we attribute this to the very significant hospital resources that are often used to care for the sickest patients in the emergency department. We also note that level 5 Type B emergency department visits account for less than 2 percent of total Type B emergency department visits, while level 5 Type A emergency department visits account for over 12 percent of total Type A emergency department visits, suggesting that for these intensive visits Type B emergency departments may be less able to benefit from efficiencies that may result from the proportionately higher volumes of lower level services in Type B emergency departments.

Comment: Some commenters are still concerned about the definition of a Type B emergency department and offered various suggestions for refining the definition. Most of these commenters requested that CMS adjust the policy to broaden the definition of Type A emergency departments, specifically to revise the rule that hospitals must carve out portions of the emergency department that are not available 24 hours a day. The commenters specifically requested that the definition be adjusted so that a ''fast track'' area of an emergency department, located within the same building as a Type A emergency department, would be considered Type A, regardless of its hours of operation, if it provides unscheduled emergency services and shares a common patient registration system with the Type A emergency department. These commenters also recommended that CMS analyze whether cost differences between Type A and Type B emergency departments result from varying contractor criteria as to what defines a Type A and Type B emergency department. One commenter suggested that we restrict the billing of Type B emergency department visit codes to emergency departments whose ''host provider'' is classified as a Type A emergency department.

Response: We consider the main distinguishing feature between Type A and Type B emergency departments to be the full-time versus part-time availability of staffed areas for emergency medical care, not the process of care or the site of care (on the hospital's main campus or offsite). We continue to believe, and as our CY 2007 claims data reflect, emergency departments or areas of the emergency department that are available less than 24 hours a day for visits of lower intensity have lower resource costs than emergency departments or areas of the emergency department that are available 24 hours a day. We have gathered 2 years of cost data based on the current definition and do not believe a policy change in the reporting of these Type A and Type B emergency department codes would be appropriate for CY 2009. In addition, if our Type A emergency department payments provide support for 24 hours a day, 7 days per week availability of services, then visits provided in areas of the hospital that are not staffed 24 hours a day could be overpaid if we were to redefine these services as Type A emergency department visits. This could also have the effect of diluting, and ultimately decreasing, the median resource costs associated with visits to Type A emergency departments.

As recommended by several commenters, we studied the cost differences between Type A and Type B emergency department visits by Medicare contractor. There were 43 contractors who handled claims from hospitals that reported both Type A and Type B emergency department visits. Our analyses revealed a distribution of visits costs as expected, including generally lower Type B emergency department visit costs in comparison with Type A emergency department visits, and increasing costs for Type B emergency department visits from levels 1 through 5, similar to the cost increases we observed for levels 1 through 5 Type A emergency department visits. There were several contractors with more unusual cost distributions for Type B emergency department visits, such as relatively similar costs across levels 1 through 5 visits for Type B emergency department visits, and we will continue to monitor these distributions in future years. While there are some limitations to our claims data, including that this is the first year of claims for the Type B emergency department visit HCPCS G-codes, that there are relatively small numbers of claims for Type B emergency department visits from CY 2007, and that certain hospitals began transitioning from fiscal intermediaries to MACs during CY 2007 and, therefore, may have received different contractor instructions during the claims year, overall, we have no reason to believe that the cost differences between Type A and Type B emergency departments evident in our aggregate OPPS claims data result from varying contractor criteria as to what defines Type A and Type B emergency departments. At this

time, we see no reason to modify our reporting instructions for Type A and Type B emergency department visits for CY 2009, and we see no evidence from the claims data available to date of markedly different interpretations of our national reporting instructions by Medicare contractors.

Comment: Several commenters expressed disappointment that CMS created Level II HCPCS G-codes for reporting Type B emergency department visits, an act which they believe is inconsistent with previous statements made by CMS that new codes would not replace existing CPT codes until national guidelines were implemented.

Response: We acknowledge that there may be some administrative burden for providers to bill HCPCS G-codes to report visits provided in Type B emergency departments rather than CPT codes. We first established these Level II HCPCS codes in CY 2007 and we will continue their use for the third year, in CY 2009. In this case, because current CPT emergency visit codes do not describe services provided in Type B emergency departments, we saw no alternative other than to create HCPCS G-codes in order to collect cost information specific to these Type B emergency department visits that would allow us to consider payment other than at the clinic visit rates which would have resulted from the continued reporting of these visits as clinic visits. In response to commenters past concerns about HCPCS G-codes, we have previously stated (71 FR 68127) that we would postpone implementing HCPCS G-codes for clinic and Type A emergency department visits until national guidelines have been established. At such time, we will again consider their possible utility.

Comment: Many commenters supported CMS' proposal to include HCPCS code G0384 in the criteria that determine eligibility for payment of the Level II Extended Assessment and Management Composite APC 8003.

Response: We are pleased that the commenters support the proposal to include HCPCS code G0384 as part of the criteria for payment of APC 8003. We believe that it is appropriate to provide payment of composite APC 8003 in those cases of an intensive level 5 Type B emergency department visit in association with 8 or more hours of observation care, when the other criteria for payment of composite APC 8003 are met. This parallels our treatment of CPT code 99285 for hospital reporting of level 5 Type B emergency department visits and payment of composite APC 8003.

We refer readers to section II.A.2.e.(1) of this final rule with comment period for further discussion related to the extended assessment and management composite APCs. As discussed in detail in section II.A.2.e.(1) of this final rule with comment period and consistent with our CY 2008 practice, when calculating the median costs for the Type A and Type B emergency visit APCs (0609 through 0616 and 0626 through 0629), we are utilizing our methodology that excludes those claims for visits that are eligible for payment through the extended assessment and management composite APC 8003. We believe that this approach results in the most accurate cost estimates for APCs 0609 through 0616 and 0626 through 0629 for CY 2009.

In summary, for CY 2009, we are finalizing our CY 2009 proposal, without modification, and adopting 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. Furthermore, we are also finalizing our CY 2009 proposal to include HCPCS code G0384 for reporting level 5 Type B emergency department visits as part of the criteria for payment of the Level II Extended Assessment and Management Composite APC 8003.

3. Visit Reporting Guidelines

As described in section IX.A. of this final rule with comment period, 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.

As noted in detail in section IX.C. of 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 thought 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 once again examined the distribution of clinic and Type A emergency department visit levels based upon updated CY 2007 claims data available for the CY 2009 OPPS/ASC 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 2009 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. We do not expect to see an increase in the proportion of visit claims for high level visits as a result of the new extended assessment and management composite APCs 8002 and 8003 adopted for CY 2008 and finalized for CY 2009. Similarly, we expect that hospitals will not purposely change their visit guidelines or otherwise upcode clinic and emergency department visits reported with observation care solely for the purpose of composite APC payment. As stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66648), we expect to carefully monitor any changes in billing practices on a service-specific and hospital-specific level to determine whether there is reason to request that Quality Improvement Organizations (QIOs) review the quality of care furnished, or to request that Benefit Integrity contractors or other contractors review the claims against the medical record.

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 local fiscal intermediary or Medicare Administrative Contractor (MAC).

Comment: Several commenters noted that they are eagerly awaiting implementation of national guidelines, particularly because of the various problems that they believe exist due to the lack of national guidelines. Some of these commenters noted that some Medicare contractors use their own auditing methods rather than reviewing each hospital's internal guidelines while conducting medical review. These commenters requested that CMS require contractors to apply a hospital's internal guidelines while performing medical review. Another commenter performed extensive review on a large sample of hospital emergency department visits to determine whether the distributions seen in this sample resembled the distribution described by CMS and printed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66804). The commenter explained that the results are similar to those of CMS at the national level, but that emergency departments have increased the proportion of level 4 and 5 emergency department visits in recent years, and that several outlier providers are billing significantly higher level visits than expected based on their geographic location and hospital type. Therefore, the commenter concluded that national guidelines would yield more accurate payment and would benefit all parties involved. The commenter also did not believe that all hospitals' internal guidelines fully comply with all the principles articulated by CMS. Other commenters supported moving cautiously toward implementation of national guidelines, acknowledging that implementation of national guidelines would create a major burden for hospitals. One commenter submitted a set of wound care guidelines for review by CMS. Many commenters requested that the AMA create CPT codes to report hospital-specific visits, after national guidelines are developed.

A few commenters recommended that, in the absence of national guidelines, CMS provide additional guidance relating to the specific services that should be included or bundled into the visit codes. One commenter specifically asked CMS to clarify what services are included in the reporting of critical care.

Response: We acknowledge that it would be desirable to many hospitals to have national guidelines. However, we also understand that it would be disruptive and administratively burdensome to other hospitals that have successfully adopted internal guidelines to implement any new set of national guidelines while we address the problems that would be inevitable in the case of any new set of guidelines that would be applied by thousands of hospitals. As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66806), we encourage fiscal intermediaries and MACs to review a hospital's internal guidelines when an audit occurs. We appreciate the visit level distribution analysis provided to us by one commenter and note that 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. We plan to specifically analyze the Type B emergency department distributions when additional years of data are available. We do not expect to see significant increases in volume for high level Type B emergency department visits as a result of the CY 2009 payment policy for these visits, which pays more for these visits in CY 2009 than in CY 2008. In addition, we reiterate our expectation that hospitals' internal guidelines fully comply with the principles listed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 68805). We appreciate receiving the set of wound care guidelines and will take these into consideration as we pursue implementation of national guidelines. We agree with the commenter that it is unlikely that one set of guidelines could be applied to visits to all HOPDs of the hospital, including specialty clinics.

Regarding the public comments requesting clarification of services that should be included or bundled into visit codes, hospitals should separately report all HCPCS codes in accordance with correct coding principles, CPT code descriptions, and any additional CMS guidance, when available. Specifically with respect to CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes), hospitals must follow the CPT instructions related to reporting that CPT code. Any services that CPT indicates are included in the reporting of CPT code 99291 should not be billed separately by the hospital. In establishing payment rates for visits, CMS packages the costs of certain items and services separately reported by HCPCS codes into payment for visits according to the standard OPPS methodology for packaging costs as outlined in sections II.A.2. and II.A.4. of this final rule with comment period.

Correct reporting by hospitals ensures the integrity of our CMS cost data. CMS developed the National Correct Coding Initiative (NCCI) to promote national correct coding methodologies and to prevent improper coding that could lead to inappropriate Part B payments. Medicare contractors implement NCCI edits in their systems for purposes of physician payment, and a subset of NCCI edits, commonly referred to as CCI edits, is incorporated into the I/OCE for claims processed through that system. While CMS currently applies CCI edits for many services under the OPPS but has temporarily suspended the application of certain edits for a period of time to allow hospitals to incorporate coding for these types of services in

their systems, CMS plans to soon apply all appropriate CCI edits for purposes of hospital reporting.

We refer readers to the July 2008 OPPS quarterly update, Transmittal 1536, Change Request 6094, issued on June 19, 2008, for further clarification about the reporting of CPT codes for hospital outpatient services paid under the OPPS. In that transmittal, we note that while CPT codes generally are created to describe and report physician services, they are also used by other providers/suppliers to describe and report services that they provide. Therefore, the CPT code descriptors do not necessarily reflect the facility component of a service furnished by the hospital. Some CPT code descriptors include reference to a physician performing a service. For OPPS purposes, unless indicated otherwise, the usage of the term ''physician'' does not restrict the reporting of the code or application of related policies to physicians only, but applies to all practitioners, hospitals, providers, or suppliers eligible to bill the relevant CPT codes pursuant to applicable portions of the Act, the CFR, and the Medicare rules. In cases where there are separate codes for the technical component, professional component, and/or complete procedure, hospitals should report the code that represents the technical component for their facility services. If there is no separate technical component code for the service, hospitals should report the code that represents the complete procedure. Consistent with past input we have received from many hospitals, hospital associations, the APC Panel, and others, we will continue to utilize CPT codes for reporting services under the OPPS whenever possible to minimize hospitals' reporting burden. If the AMA were to create facility-specific CPT codes for reporting visits provided in HOPDs, we would certainly consider such codes for OPPS use.

Comment: One commenter asked whether it was appropriate for a hospital to bill a visit code under the OPPS for care provided to a registered outpatient if the patient was not seen by a physician.

Response: Under the OPPS, unless indicated otherwise, we do not specify the type of hospital staff (for example, nurses or pharmacists) who may provide services in hospitals because the OPPS only makes payments for services provided incident to physicians' services. Hospitals providing services incident to physicians' services may choose a variety of staffing configurations to provide those services, taking into account other relevant factors such as State and local laws and hospital policies.

Billing a visit code in addition to another service merely because the patient interacted with hospital staff or spent time in a room for that service is inappropriate. A hospital may bill a visit code based on the hospital's own coding guidelines which must reasonably relate the intensity of hospital resources to different levels of HCPCS codes. Services furnished must be medically necessary and documented.

Comment: Several commenters requested that CMS allow hospitals to bill critical care with a minimum time requirement of 15 minutes rather than the current 30 minute time requirement. The commenters noted that the hospital may have its greatest resource use in the first 10 minutes of critical care which is much earlier than the 30 minute minimum required in the CPT code descriptor.

Response: The CPT instructions for reporting of critical care services with CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes) and the CPT code descriptor specify that the code can only be billed if 30 minutes or more of critical care services are provided. Because hospitals will be reporting CPT codes for critical care services for CY 2009, they must continue to provide a minimum of 30 minutes of critical care services in order to bill CPT code 99291, according to the CPT code descriptor and CPT instructions. We note that hospitals can report the appropriate clinic or emergency department visit code consistent with their internal guidelines if fewer than 30 minutes of critical care is provided.

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 our moving 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 that may arise 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 will not implement national guidelines prior to CY 2010. 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 visits in hospital outpatient settings.

X. 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 beneficiaries who have an acute mental illness. 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 Medicare regulations at § 419.21(c) that implement this provision specify that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs as well as those furnished to hospital outpatients. Section 1833(t)(2)(C) of the Act requires that we establish relative payment weights based on median (or mean, at the election of the Secretary) hospital costs determined by 1996 claims data 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 APC, effective for services furnished on or after August 1, 2000 (65 FR 18452).

Historically, the median per diem cost for CMHCs greatly exceeded the median per diem cost for hospital-based PHPs and fluctuated significantly from year to year, while the median per diem cost for hospital-based PHPs remained relatively constant ($200-$225). We believe that CMHCs may have increased and decreased their charges in response to Medicare payment policies. As discussed in more detail in section X.B. of this final rule with comment period and in the CY 2004 OPPS final rule with comment period (68 FR 63470), we also believe that some CMHCs manipulated their charges in order to inappropriately receive outlier payments.

In the CY 2005 OPPS update, which was based on CY 2003 data, the CMHC median per diem cost was $310, the hospital-based PHP median per diem

cost was $215, and the combined CMHC and hospital-based median per diem cost was $289, a reduction in median cost from previous years. We believed the reduction indicated that the use of updated CCRs had accounted for the previous increase in CMHC charges and represented a more accurate estimate of CMHC per diem costs for PHP.

For the CY 2006 OPPS final rule with comment period, which was based on CY 2004 data, the median per diem cost for CMHCs dropped to $154, while the median per diem cost for hospital-based PHPs was $201. We believed that a combination of reduced charges and slightly lower CCRs for CMHCs resulted in a significant decline in the CMHC median per diem cost between CY 2003 and CY 2004.

The CY 2006 OPPS updated combined hospital-based and CMHC median per diem cost was $161, a decrease of 44 percent compared to the CY 2005 combined median per diem amount. Due to concern that this amount may not have covered the cost for PHPs, as stated in the CY 2006 OPPS final rule with comment period (70 FR 68548 and 68549), we applied a 15-percent reduction to the combined hospital-based and CMHC median per diem cost to establish the CY 2006 PHP APC. (We refer readers to the CY 2006 OPPS final rule with comment period for a full discussion of how we established the CY 2006 PHP rate (70 FR 68548).) In that rule, we stated our belief that a 15-percent reduction in the CY 2005 median per diem cost would strike an appropriate balance between using the best available data and providing adequate payment for a program that often spans 5–6 hours a day. We stated that 15 percent was an appropriate reduction because it recognized decreases in median per diem costs in both the hospital data and the CMHC data, and also reduced the risk of any adverse impact on access to these services that might result from a large single-year rate reduction. However, we adopted this policy as a transitional measure, and stated in the CY 2006 OPPS final rule with comment period that we would continue to monitor CMHC costs and charges for these services and work with CMHCs to improve their reporting so that payments could be calculated based on better empirical data (70 FR 68548). To apply this methodology for CY 2006, we reduced the CY 2005 combined unscaled hospital-based and CMHC median per diem cost of $289 by 15 percent, resulting in a combined median per diem cost of $245.65 for CY 2006.

For the CY 2007 OPPS/ASC final rule with comment period, we analyzed hospital and CMHC PHP claims for services furnished between January 1, 2005, and December 31, 2005, and used the most currently available CCRs to estimate costs. The median per diem cost for CMHCs was $173, while the median per diem cost for hospital-based PHPs was $190.

The combined hospital-based and CMHC median per diem cost would have been $175 for CY 2007. Rather than allowing the PHP per diem rate to drop to this level, we proposed to reduce the PHP median cost by 15 percent, similar to the methodology used for the CY 2006 update. However, after considering all of the public comments received concerning the proposed CY 2007 PHP per diem rate and results obtained using more current data, we modified our proposal. We made a 5-percent reduction to the CY 2006 median per diem rate to provide a transitional path to the per diem cost indicated by the data. This approach accounted for the downward direction of the data and addressed concerns raised by commenters about the magnitude of another 15-percent reduction in 1 year. Thus, to calculate the CY 2007 APC PHP per diem cost, we reduced $245.65 (the CY 2005 combined hospital-based and CMHC median per diem cost of $289 reduced by 15 percent) by 5 percent, which resulted in a combined per diem cost of $233.37.

For the CY 2008 OPPS/ASC final rule with comment period, we analyzed 12 months of current data for hospital-based PHP claims (condition code 41) and CMHC PHP claims for PHP services furnished between January 1, 2006, and December 31, 2006. We also used the most currently available CCRs to estimate costs for a day of PHP services. The median per diem cost for CMHCs was $172, while the median per diem cost for hospital-based PHPs was $177. The combined median per diem cost, which was computed from both hospital-based and CMHC PHP data, was $172.

For the prior 3 years, we have been concerned that we did not have sufficient evidence to support using the median per diem cost produced by the most current year's PHP data. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66671), after extensive data analysis, we believed the data reflect the level of cost for the type of services that were being provided. This analysis included an examination of revenue-to-cost center mapping, refinements to the per diem methodology, and an in-depth analysis of the number of units of services per day. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66671 through 66675) for a detailed discussion of the data analysis.)

For CY 2008, we proposed and finalized two refinements to the methodology for computing the PHP median. However, these refinements did not appreciably impact the median per diem cost. We remapped the 10 revenue codes to the most appropriate cost centers and computed the median using a per day methodology (as described below). As noted in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66671), after extensive analysis, we believed the data reflected the level of cost for the type of services that were being provided. We continued to observe a clear downward trend in the CY 2006 data used to develop the CY 2008 OPPS/ASC final rule with comment period.

Thus, for CY 2008, we refined our methodology for computing PHP per diem costs. We developed an alternate method to determine median cost by computing a separate per diem cost for each day rather than for each bill. Under this method, we computed a cost separately for each day of PHP care. When there were multiple days of care entered on a claim, a unique cost was computed for each day of care. We only assigned costs for line items on days when a payment was made. All of these costs were then arrayed from lowest to highest and the middle value of the array was considered the median per diem cost. A complete discussion of the refined method of computing the PHP median cost can be found in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66672).

Because partial hospitalization is provided in lieu of inpatient care, it should be a highly structured and clinically-intensive program, usually lasting most of the day. Our goal is to improve the level of service furnished in a PHP day. For CY 2008, we were concerned that the proposed decrease in PHP payment might not have reflected the mix and quantity of services that should be provided under such an intensive program. In an effort to ensure access to this needed service to vulnerable populations, we mitigated the proposed reduction to 50 percent of the difference between the CY 2007 APC amount ($233) and the computed amount based on the PHP data ($172), resulting in an APC median cost of $203 for CY 2008. As stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66673), we believed this payment amount would give the providers an opportunity to increase the intensity of their programs and maintain

partial hospitalization as part of the continuum of mental health care.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66673), we reiterated our expectation that hospitals and CMHCs will provide a comprehensive program consistent with the statutory intent. We also indicated that we intend to explore changes to our regulations and claims processing systems in order to deny payment for low intensity days.

B. PHP APC Update

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66672 through 66674), we presented our analysis of the number of units of service provided in a day of care, as a possible explanation for the low per diem cost for PHP. Both hospital-based and CMHC PHPs had a significant number of days where fewer than 4 units of service were provided. As noted in the CY 2008 OPPS/ASC final rule with comment period, review of CY 2006 data showed that 64 percent of the CMHC days were days where fewer than 4 units of service were provided, and 31 percent of the hospital-based PHP days were days where fewer than 4 units of service were provided (72 FR 66672).

As discussed in the CY 2009 OPPS/ASC proposed rule (73 FR 41513), we have updated this analysis using updated CY 2007 claims and found that the results and trends have continued for CMHCs. In fact, there are even more days with less than 4 units of service provided in CMHCs; however, there are fewer days with less than 4 units of service provided in hospital-based PHPs compared to the CY 2006 data. Using CY 2007 claims, 73 percent of CMHC days have fewer than 4 units of service, and 29 percent of hospital-based PHP days have fewer than 4 units of service. Based on these updated findings, we computed median per diem costs in the following three categories: (1) All days; (2) days with 3 units of service; and (3) days with 4 units or more of service. These updated median per diem costs were computed separately for CMHCs and hospital-based PHPs and are shown in the table below:

	CMHCs	Hospital-based PHPs	Combined
All Days	$145	$174	$148
Days with 3 units	139	157	139
Days with 4 units or more	172	200	174

Using updated CY 2007 data and our refined methodology for computing PHP per diem costs adopted in our CY 2008 OPPS/ASC final rule with comment period (72 FR 66672), the median per diem cost calculated from all claims is $148. Using the updated CY 2007 data, the trends noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41513) have continued. The updated CY 2007 data indicate that CMHCs provide far fewer days with 4 or more units of service and that CMHC median per diem cost ($145) is substantially lower than the comparable data from hospital-based PHPs ($174). Medians for claims containing 4 or more units of service are $200 for hospital-based PHPs and $174 for all PHP claims regardless of site of service. Medians for claims containing 3 units of service are $139 for CMHCs, $157 for hospital-based PHPs, and $139 for all PHP claims regardless of site of service.

As we stated in our CY 2008 OPPS/ASC final rule with comment period (72 FR 66672), it was never our intention that days with only 3 units of service should represent the number of services provided in a typical day. Our intention was to cover days that consisted of 3 units of service only in certain limited circumstances. For example, as we noted in the CY 2009 OPPS/ASC proposed rule, we believe 3-service days may be appropriate when a patient is transitioning towards discharge (or days when a patient who is transitioning at the beginning of his or her PHP stay). Another example of when it may be appropriate for a program to provide only 3 units of service in a day is when a patient is required to leave the PHP early for the day due to an unexpected medical appointment (73 FR 41513). Therefore, we recognize there may be limited circumstances when it is appropriate for PHPs to receive payment for days when only 3 units of service are provided. However, as we indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41513), we believe that programs that provide 4 or more units of service should be paid an amount that recognizes that they have provided a more intensive day of care. A higher rate for more intensive days is consistent with our goal that hospitals and CMHCs provide a comprehensive program in keeping with the statutory intent.

Accordingly, although there are circumstances when 3 units of service provided may be appropriate, in order to reflect our general belief that 4 or more units of service more appropriately reflect the comprehensive nature of PHP services, for CY 2009, we proposed to create two separate APC payment rates for PHP: One for days with three services (APC 0172) and one for days with four or more services (APC 0173). For APC 0172, we proposed to use the median per diem cost for CMHC and hospital-based PHP days with 3 units of services ($140). For APC 00173, we proposed to use the median per diem cost for CMHC and hospital-based PHP days with 4 or more units of service ($174). As noted previously, these proposed payment rates are derived from both PHP-based and CMHC-based claims, and represent the median cost of providing PHP services for the unit of services described.

Comment: A number of commenters expressed concern about the magnitude of the PHP per diem rate reduction, particularly in light of reductions over the past few years (50 percent over 5 years). Many commenters believed that a reduction of 14.2 percent for CY 2009 would reduce the financial viability of PHP and possibly lead to the closure of many PHPs, thus affecting access to this crucial service that serves vulnerable populations. In addition, because hospital outpatient mental health services paid under the OPPS are capped at the PHP per diem rate, many commenters were concerned about overall access to outpatient mental health treatment. The majority of the commenters requested that CMS adjust the rate upward or freeze the PHP per diem rate at the CY 2008 level. Some commenters suggested leaving Level II services at the current rate, but reduce the rate for the Level I PHP services as proposed.

Several commenters requested that CMS withdraw the provisions pertaining to the proposal to create two separate APCs. The commenters stated that the split mechanism could encourage providers to provide patients with fewer services. Other commenters supported creation of a Level I PHP day,

stating that the two-tier payment proposal is good but does not go far enough to promote service intensity and continued access to their important services.

Many of the commenters supported the creation of two separate APC payment rates for PHPs based on the number of units of service provided to a patient per day but recommended that CMS use only hospital-based PHP data to determine the rates at which PHP services will be paid in hospital-based settings. These commenters believed that hospital-based data are reliable, predictable, and national in scope.

The commenters pointed out that while the aggregate number of PHP service providers has remained relatively stable over time, the number of hospital-based PHPs has dropped by 16 percent, while the number of CMHC PHPs has increased by 53 percent (with the majority of new CMHCs located in Florida, Louisiana, and Texas). The commenters reported that 80 percent of the States have two or more hospital programs, and only 30 percent of the States have more than one CMHC. The commenters believed that it is also important to note that the number of rural hospital-based PHPs has declined during the 2003–2006 period by 47 percent.

Response: After consideration of the public comments received on the two-tiered payment approach, we have decided to retain the two-tiered payment approach in order to provide PHPs scheduling flexibility to ensure that patients receive at least 20 hours of therapeutic services per week and to reflect the lower costs of a less intensive day. Although we do not expect Level I days to be frequent, we do recognize that there are times when a patient may need a less intensive day. Therefore, we recognize the need for a two-tiered payment system: One payment for those less intensive days with three services and another payment for those more intensive days with four or more services. We believe that were a PHP to provide only Level I days to a patient, it would be difficult for the patient to meet the eligibility criteria in 42 CFR 410.43 requiring a minimum of 20 hours of service per week (discussed later in this section).

We understand the commenters' concerns over the magnitude of the PHP per diem rate reduction and the impact the reduction has on the payment cap for other hospital outpatient mental health services. We also understand the commenters' concerns regarding continued access to the PHP benefit, particularly in hospital-based PHPs, which we believe are generally providing the mix and quantity of services that should be provided under such an intensive program.

Hospital-only data have been used in the past to set the PHP payment rates when the CMHC data were unavailable or too volatile to use. This year, using the CMHC data would significantly reduce the current rate and negatively impact hospital-based PHPs, resulting possibly in reduced access to care. Because hospital-based PHPs are geographically diverse, whereas CMHCs are located in only a few States, we are concerned that a significant drop in the rate could result in hospital-based PHPs closing and leading to possible access problems. In addition, using hospital-based PHP data alone results in a Level II Partial Hospitalization rate (APC 0173) that is close to the current payment level ($203).

In light of the reasons noted above, we are finalizing the two-tiered payment rates as proposed, but are instead using hospital-based PHP data only to calculate the two per diem payment rates. As we stated earlier in this section and in the CY 2009 OPPS/ASC proposed rule, although there are circumstances when 3 units of service provided may be appropriate, in order to reflect our general belief that 4 or more units of service more appropriately indicated the comprehensive nature of PHP services, for CY 2009, we are creating two separate APC payment rates for PHP: One for days with three services and one for days with four or more services. We are finalizing two new APCs for PHP as follows:

APC	Group title	Per diem rate
0172	Level I Partial Hospitalization (3 services)	$157
0173	Level II Partial Hospitalization (4 or more services)	200

For APC 0172, we are using the median per diem cost for hospital-based PHP days with 3 units of services ($157). For APC 00173, we are using the median per diem cost for hospital-based PHP days with 4 or more units of service ($200). These payment rates are derived from hospital-based PHP claims, and represent the median cost of providing PHP services for the unit of services described. We believe that creating a rate specific to days with three services is consistent with our policy to require CMHCs and hospital-based PHPs to provide a minimum of 3 units of service per day in order to receive payment as discussed below in section X.C.1. of this final rule with comment period. Creating two separate PHP rates provides a lower payment for days with only 3 units of services, while not penalizing programs that provide four or more units of service by excluding days with 3 units of service in the computation of APC 0173. As we stated in the CY 2009 OPPS/ASC proposed rule, we believe this two-tiered approach appropriately balances our concern that a PHP is an intensive program and should generally consist of 5 to 6 units of service, with the realization that there may be certain appropriate circumstances where 3 units of service may be provided in a day.

As the PHP rates are applied to both CMHC and hospital-based PHPs, we would prefer to use both hospital-based PHP and CMHC data in computing the PHP rates. The changes we are making with respect to the PHP benefit, providing a two-tiered payment approach, clarifying eligibility criteria and denying payment for low intensity days, are expected to create more comparable programs in terms of the number of units furnished in a typical day for both CMHCs and hospitals. We believe that these efforts also will reduce the difference in the median cost per day in these two settings over time and CMHC data will be available for future ratesetting.

Comment: A few commenters requested that CMS further consider separate payment rates for PHP provided in CMHCs versus hospital-based programs, given the significant difference in costs for providing those services in the two settings. The commenters suggested that CMS establish a total of four distinct rates based upon claim data. The commenters gave the following example: CMHC—Level I 3 services, $139; CMHC—Level II 4 or more services, $171; HB—Level

I 3 services, $151 and; HB—Level II 4 or more services, $205.

Response: We appreciate this comment, and we continue to evaluate ways to better reflect the costs in providing PHP services.

Comment: A few commenters disagreed with the CMS approach to establishing the median per diem cost by summarizing the line-item costs on each bill and dividing by the number of days on the bills. The commenters indicated that this calculation can severely dilute the rate and penalize providers. The commenters stated that all programs are strongly encouraged by the fiscal intermediaries to submit all PHP service days on claims, even when the patient receives less than 3 units of service. The commenters were concerned that programs are only paid their per diem when 3 or more qualified units of service are presented for a day of service. The commenters stated that if only 1 or 2 units of service are assigned a cost and the day is divided into the aggregate data, the cost per day is significantly compromised and diluted. They claimed that even days that are paid but only have 3 units of service dilute the cost factors on the calculations.

One commenter suggested that the CMS' methodology is flawed because it does not reflect actual costs. One commenter expressed the view that the CMS methodology for rate calculations using CCRs does not fairly reflect the actual costs of the providers. The commenter stated that, with the change to per diem payment in 2000, the CCRs do not have the same influence on services that they did under cost-based reimbursement. The commenter noted that, other than the reporting in the cost reports, the charge factor has no bearing on the services. The commenter believed that, regardless of the charge, payment is still made at the established rate influenced only by the wage index. The commenter stated that the higher the ''charge'' established by the provider and reported in the cost report, the lower the proportionate rate of cost is assigned by CMS when calculating the costs to determine the median cost rates. The commenter stated that hospitals and CMHCs can drastically influence the rates innocently, by the identification of the charge per service assigned to the particular intervention. The commenter mentioned that providers have unknowingly hurt their own programs by raising their identified charges for a service, as this lowers the percentage of the applicable ratio when applied to the claim services. The commenter stated that the charges themselves have no bearing whatsoever on the delivery or provision of the services.

Response: We expect that a provider's charges will reflect the level of services provided, which has a relationship to the cost of providing those services. In Medicare cost reporting, the total charges are to be reported along with the provider's cost. To the extent that a provider is submitting bills that have charges that do not directly relate to the delivery or provision of services, their CCRs will be unpredictable and would distort the costs of the services provided.

Moreover, in developing the CY 2009 PHP rates, we excluded days that have only 1 or 2 units of service. In addition, we did not include days where no payment was made. This resulted in our using data only from those days where we believe PHP services were actually provided. To calculate the Level I PHP rate, we used days with 3 units of service, and to calculate the Level II PHP rate, we used days with 4 or more units of service. We believe our methodology accurately reflects the median cost of providing these two levels of PHP.

As discussed in the CY 2008 OPPS final rule with comment period (72 FR 66671–66672), we have refined our methodology for computing per diem costs. We have developed an alternate way to determine median cost by computing a separate per diem cost for each day rather than for each bill and, in so doing, we believe it more accurately reflects the per diem cost of providing PHP services. Under this method, a cost is computed separately for each day of PHP care. When there are multiple days of care entered on a claim, a unique cost is computed for each day of care. We only assign costs for line items on days when a payment is made. All of these costs are then arrayed from lowest to highest and the middle value of the array would be the median per diem cost.

We adopted this alternative method of computing PHP per diem median cost because we believe it produces a more accurate estimate because each day gets an equal weight towards computing the median. This method for computing a PHP per diem median cost more accurately reflects the costs of a PHP day and uses all available PHP data. In addition, if a provider has charges on a bill for which the provider does not receive payment, this will be reflected in that provider's CCRs. This lower CCR will be applied to the larger charges and will result in the appropriate cost per diem.

Comment: Several commenters asked CMS to analyze the mapping of revenue-codes-to-cost centers for CMHCs similar to the analysis CMS completed for hospital-based programs and discussed in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68000). The commenters indicated that CMHC PHP services have higher CCRs than the overall CMHC CCRs.

Response: We cannot conduct a revenue code mapping analysis for CMHCs because PHP is the CMHCs' only Medicare cost, and CMHCs do not have the same cost centers as hospitals. Therefore, for CMHCs, we use the overall facility CCR from the Outpatient Provider-Specific File.

Comment: One commenter stated that two of the PHP codes, activity therapy and education and training, are allowed to be performed multiple times per day, but only count as one therapy unit, regardless of how many sessions are actually provided.

Response: As we have stated in the past, there is a misconception that CMS only counts activity therapy and education and training services as one therapy unit, regardless of how many sessions are actually performed. We again note that when the PHP per diem is calculated, all therapy sessions are counted in the analysis. When we established HCPCS code G0176 for activity therapy, we defined the code as ''Activity therapy, such as music, dance, art or play therapies not for recreation, related to the care and treatment of patient's disabling mental problems, per session (45 minutes or more).'' In addition, when we established HCPCS code G0177 for education and training, we defined the code as ''Training and educational services related to the care and treatment of patient's disabling mental health problems, per session (45 minutes or more).'' Therefore, when PHPs provide and bill for multiple sessions of HCPCS codes G0176 and G0177, they are counted as multiple therapy units.

Comment: Many commenters stated that, as CMS is aware, cost report information for CMHCs is not currently included in the Healthcare Cost Report Information System (HCRIS) and recommended that CMS base its calculations only in the cost report information that the agency can verify directly and not on data provided by the fiscal intermediary.

Response: We understand the commenters' need to have CMHC data available through the HCRIS system and are working to include them in the system. However, we have no reason to believe the Medicare contractors enter incorrect CCRs in the Outpatient Provider Specific File.

Comment: With respect to the methodology used to establish the PHP APC amount, commenters were concerned that data from settled cost reports do not include costs reversed on appeal. The commenters stated that there are inherent problems in using claims data from a time period that is different from that for the CCRs from settled cost reports. They indicated that this methodology would artificially lower the computed median costs, and that the data used to calculate the PHP rate should be revised to include costs that were subsequently allowed. The commenters also stated that CMS uses costs that are at least 1 to 3 years old to project rates 2 years forward and that this approach does not accurately reflect the true costs of the providers.

Response: Since 2000, Medicare has paid for PHP through the OPPS, which is not a cost-based reimbursement system. We use the best available data in computing the APCs. On January 17, 2003, we issued Program Memorandum No. A–03–004 that directed fiscal intermediaries to update the CCRs on an ongoing basis whenever a more recent full year settled or tentatively settled cost report is available. In this way, we minimize the time lag between the CCRs and claims data and continue to use the best available data for ratesetting purposes.

Comment: A few commenters expressed their concern as to why CMS continues to state that a day of partial hospitalization should not equal the cost of the separate services provided in a non-PHP setting or that even a full partial day should not equal the cost of the separate services in an outpatient hospital setting. These commenters presented two different typical days using proposed CY 2008 rates: Typical Day 1 included three group therapy sessions (CPT code 90853, APC 0325, 3 × $64.45) and one individual psychotherapy session (CPT code 90818, APC 0323, $106.49). The commenter priced Typical Day 1 at $299.84. Typical Day 2 included one group therapy session (CPT code 90853, APC 0325, $64.45), one individual psychotherapy session (CPT code 90818, APC 0323, $106.49), and one family therapy session (CPT code 90847, APC 0324, $141.61). The commenter priced Typical Day 2 at $312.55. Based on the commenter's presented material, the commenter stated that the typical days yield an average componentized rate of $306. The commenter questioned how CMS can set rates for APCs 0322 through 0325, but is unable to determine a payment rate for a day that is comprised of a minimum of 3 to 4 units of those services. Other commenters stated that while CMS requires a minimum of four treatments per day to qualify for a day of PHP, the proposed per diem rate of $179.88 for PHP is less than what CMS would pay for four group therapy sessions.

Some commenters mentioned variations of using the median cost of $62.66 for APC 325 to illustrate the inadequacy of the proposed PHP per diem payment of $174.07. One commenter stated that by multiplying 4 group therapy services by $62.66 yields $250.64, which is more that $174.07. Another commenter claimed that CMS pays hospital facilities for outpatient services on a per unit basis up to the per diem PHP payment. The commenter mentioned that CMS has identified Group Therapy APC 0325 with a true median cost of $62.66. The commenter stated that the patients involved in outpatient services are participating 1 to 3 days and generally receive 4 or more units of service on those days. The commenter added that while programs are providing 4 or more units of service, the per diem limit will only allow them to be ''paid their cost'' for about 2.75 units of service (3 × $62.66 = $187.98). The commenter stated that the program is $13.91 short for the third service and the fourth service and any others are provided with no reimbursement.

Response: We do not believe that it is appropriate to compare the partial hospitalization services to separate mental health services. The commenter does not use the payment rates for the PHP APCs, that is, APCs 0172 and 0173, in its calculations. The payment rates for APC services cited by the commenter (APC 0323, APC 0324, and APC 0325) are not computed from PHP bills. As stated earlier, we used data from PHPs to determine the median cost of a day of PHP. PHP is a program of services where savings can be realized by hospitals and CMHCs over delivering individual psychotherapy services.

We structured the PHP APCs (APCs 0172 and 0173) as a per diem methodology in which the day of care is the unit that reflects the structure and scheduling of PHPs and the composition of the PHP APCs consist of the cost of all services provided each day. Although we require that each PHP day include a psychotherapy service, we do not specify the specific mix of other services provided, and our payment methodology reflects the cost per day rather than the cost of each service furnished within the day.

We examined both CMHC and hospital-based PHP data to determine what services these programs are providing to their patients. An important finding was that the ''typical'' days cited by the commenter are not typical days for most CMHCs. For CMHCs, 60 percent of services are group psychotherapy (CPT codes 90853 and 90857), 26 percent of services are training and education (HCPCS code G0177), 12 percent are activity therapy (HCPCS code G0176), and only 1 percent of PHP days included individual therapy (brief or extended (CPT code 90816 or 90818)).

The ''typical'' days cited by the commenter also are not typical days for hospital-based PHPs. For hospital-based PHPs, 47 percent of services are group psychotherapy (CPT codes 90853 and 90857), 27 percent of services are training and education (HCPCS code G0177), 16 percent are activity therapy (HCPCS code G0176), 3 percent are occupational therapy (HCPCS code G0129), 2 percent of PHP days include brief individual psychotherapy (CPT code 90816), and only 1 percent of PHP days include extended individual therapy (CPT code 90818).

We note that the APCs for training and education (HCPCS code G0177), activity therapy (HCPCS code G0176), and occupational therapy (HCPCS code G0129) are not separately payable under the OPPS. They are packaged services and only payable as part of a PHP day of care. In CMHCs, training and education (HCPCS code G0177) and activity therapy (HCPCS code G0176) account for 38 percent of PHP services. In hospital-based PHPs, training and education and activity therapy account for 43 percent of PHP services. In addition to not being separately payable, these services may be provided to patients by less costly staff than staff who provide psychotherapy and occupational therapy. Based on the mix of services provided on the majority of PHP days, we believe the data used for setting the PHP payment appropriately reflect the typical PHP day and its costs should not be compared to the costs of providing separate services.

Comment: Several commenters claimed that the costs of CMHCs are higher because ''hospitals can share and spread their costs to other departments.'' The commenters believed that the CMHC patient acuity level is more intense than that for hospital patients because HOPDs need only provide one or two therapies, yet still receive the full PHP per diem.

Response: We do not agree that CMHC costs are necessarily higher than that of a hospital. CMHCs are required to furnish an array of outpatient services, including specialized outpatient services for children, elderly persons, individuals with a serious mental illness, and residents of its service area

who have been discharged from inpatient treatment. Accordingly, CMHCs have the same ability as hospitals to share costs among its programs as needed. Further, we believe hospital costs in some areas, for example, capital and 24-hour maintenance costs, greatly exceed comparable CMHC costs. Regardless, we believe patient acuity across hospital-based and CMHC PHPs should be the same, that is, the patients would otherwise require inpatient psychiatric care regardless of setting (section 1835(a)(2)(F) of the Act).

Comment: Many commenters expressed concern that the proposed rates exclude substantial costs from the providers that should be considered for calculating the per diem PHP rates. In summary, the commenters stated ''that approximately 2.25 hours of direct services per day are provided to Medicare patients that are not billable or do not have codes available to bill Medicare.'' The commenters cited as examples: 100 percent of physician supervision and related overhead expenses; 85 to 93 percent of all nursing related direct services for physical health needs or family education services; 92 percent of case management services provided by licensed therapists and other support staff; 85 percent of unscheduled crisis intervention services; and 80 percent of family therapy without the client. Other commenters also provided specific examples of indirect services they provide that are not reimbursable, such as: assisting in finding housing; accessing other health care services; obtaining medications; working through issues with family members; providing transportation to medical and other appointments; assisting with the information and appointments regarding Social Security and Medicare questions; accessing food banks and food stamps; obtaining eye and dental services; providing occupational therapy, dual diagnosis (conducted by a licensed therapist), relaxation, humor, mindfulness, nutrition education (run by a registered dietician), pastoral care; and trying to integrate volatile/anxious patients into the milieu when they cannot tolerate a group process and need one-on-one attention.

Response: PHP services are specifically defined in section 1861(ff) of the Act. Meals and transportation are specifically excluded under section 1861(ff)(2)(I) of the Act. While some of the services the commenters list are provided in a PHP setting, we only pay for direct patient care costs. Other services, such as case management and team meetings, would be considered overhead costs and not direct patient care costs. All Medicare allowable costs will be included in the cost portion of the CCR. By applying this ratio to the billed charges, the cost estimate will reflect all allowable costs.

Comment: Many commenters expressed concern that CMS fails to protect rural mental health providers. The commenters claim that there is documented evidence, published by CMS, of the special hardships and needs of rural providers. They noted that most other rural provider types have been recognized for this hardship and have had allowance and special provisions to ensure their viability. The commenters requested that CMS consider treating CMHCs in an equitable manner to other rural provider types. The commenters also mentioned that they reviewed all of the documentation available and the impact statement, but found no evidence that any small rural providers had been included. The commenters wanted to remind CMS that the agency is required by law to calculate and disclose the impact of any action on small and rural providers. A few commenters specifically mentioned that there were no Louisiana CMHCs included in the impact.

Response: We believe we do take the concerns of rural mental health providers into account. Over the last several years, our mitigation of rate reductions for PHPs benefits all CMHCs, including rural providers. As to the particular treatment of rural providers, we believe the commenter may be referring to the statutory hold harmless provisions. Section 1833(t)(7)(D) of the Act authorizes such payments, on a permanent basis, for children's hospitals and cancer hospitals and, through CY 2009, for rural hospitals having 100 or fewer beds and is not a SCH, and for SCHs in rural areas. Section 1866(t)(7)(D) of the Act does not authorize hold harmless payments to CMHCs. In addition, another provision directed at rural providers, section 411 of Public Law 108–173 that requires CMS to determine the appropriateness of additional payments for certain rural hospitals, does not extend to CMHCs.

In this year's impact table, we included CMHCs in the total count of providers, but they are not shown separately. We typically do not report a separate impact for CMHCs because they are only paid for one service, PHP, under the OPPS, and each CMHC can typically easily estimate the impact of payment rate changes by referencing payment for PHP in Addendum A to both the proposed rule and this final rule with comment period. Because we proposed a CY 2009 policy change to PHP payment, we presented separate impacts for CMHCs in Table 45 and discussed the impact in section XXI.B.4 in the CY 2009 OPPS/ASC proposed rule (73 FR 41558). We have updated this analysis for this final rule with comment period. (For additional information, we refer readers to section XXIII of this final rule with comment period.)

Comment: Several commenters requested that CMS support a legislative amendment to remove PHP from the APC codes and create an independent status similar to home health and then establish a reasonable base rate for PHP such as the current 2008 per diem. The commenters also recommended that CMS annually adjust the base rate by a conservative inflation factor such as the CPI. Other commenters suggested establishing a PHP rate calculation task force to develop a new rate methodology that captures all relevant data and reflects the actual costs to providers to deliver PHP services. The commenter recommended that the ratesetting task force be composed of CMS staff and a diverse group of stakeholders that includes front-line providers of PHP services and representatives from national industry organizations.

Response: As the commenters stated, currently, the statutory authority does not provide for a separate payment system for partial hospitalization services. Therefore, it would require a statutory change to establish an independent payment system for PHPs. In response to commenters' request for a PHP rate calculation task force, we do not believe an official task force is required, but we continue to support an informal process. We have met with industry groups and providers numerous times over the years and continue to be open to discussion about the partial hospitalization benefit.

Comment: A few commenters recommended that CMS establish quality criteria to judge performance and that would influence future payment rates.

Response: We agree with the commenters that information about the status of quality benchmarks and indicators would be useful and we encourage providers to submit that information to us. While the commenters did not provide any specifics, we would be interested in how such a quality program would be structured.

Comment: A few commenters stated that the wage index adjustment does not accurately reflect the cost of labor in areas affected by Hurricanes Katrina and Rita. The commenters also pointed out that the proposed wage index in

Louisiana has decreased post-hurricane instead of increasing, which has resulted in a much lower payment rate in Louisiana. The commenters further stated that the time lag for wage indexing is a huge factor for Hurricane Zone providers and that the wage index decrease makes the assumption that the cost of labor has actually decreased since the hurricanes. Some commenters noted that the lack of facilities and trained professionals and inadequate reimbursement will make Louisiana worse off now than prior to Hurricanes Katrina and Rita.

Response: The hospital wage data used to compute the FY 2009 IPPS hospital wage index is from the FY 2005 hospital cost reports for all hospitals. This is the standard lag timeframe in determining the hospital wage index. The FY 2005 data are reflected in the FY 2009 IPPS hospital wage index. However, we note that the wage index is a relative measure of differences in area hourly wage levels. It compares a labor market's average hourly wage to the national average hourly wage. To the extent that post-hurricane hospital labor costs are higher relative to the national average, the wage index reflects the higher relative labor cost beginning with the FY 2005 data that are in the FY 2009 IPPS hospital wage index (which will be applied to the CY 2009 OPPS rate year). In addition, the statutory authority for the OPPS wage index policy in section 1833(t)(2)(D) of the Act requires that the wage adjustments be made in a budget neutral manner. Therefore, any increase in one wage area factor would need to be budget neutral. Finally, it should be noted that CMHCs and hospitals located in Federal Emergency Management Agency (FEMA) designated disaster areas received relief funds by the Department of Health and Human Services in 2007.

Comment: One commenter stated that CMS data and per diem payment rates are strongly biased by just a few providers. The commenter stated that CMS' data identifies 631 providers of partial hospitalization services and identifies the overall industry costs at $288 million with approximately 1,400,000 days of partial hospitalization services. The commenter stated that this suggests an average daily census per program of less than 9 patients per day, based on 250 days of services in a year. The commenter was aware of only 2 or 3 programs that maintain a daily census in PHPs in excess of 50 to 60 per day, some as high as 200 to 250 per day. The commenter stated that these individual providers skew the data and disproportionately influence the calculated rates with severe cost advantages that other providers cannot duplicate because of economies of scale. The commenter stated that these few high volume providers should not set the rates for all providers and should be excluded from the rate calculations.

Response: In response to this comment, we analyzed the cost per day for various high volume providers and determined that the high volume providers have a cost per day similar to that of smaller, lower volume providers. For this reason, although high volume providers may have a greater proportion of days used for median rate setting, we do not believe that including the data for these providers skews the resulting median. Our analysis shows that economies of scale do not appear to influence the cost per day for these providers.

Comment: One commenter expressed concern that the proposed PHP APC rate decrease is inconsistent with a response CMS gave to a MedPAC recommendation. The commenter claimed that MedPAC recommended that the Congress should increase payment rates for the acute inpatient and outpatient prospective payment systems in 2009 by the projected rate of increase in the hospital market basket index, concurrent with implementation of a quality incentive payment program. The commenter also claimed that CMS' response was that it was proposing to increase payment rates for the CY 2009 OPPS by the projected rate of increase in the hospital market basket through adjustment of the full CY 2009 conversion factor.

Response: All APCs under the OPPS receive a market basket increase as part of the calculation of the conversion factor. The proposed PHP APC rates were based upon standard OPPS ratesetting methodology. Barring a decrease due to the quality reporting requirements, we anticipate a full market basket increase and not an update of less than a full market basket to the OPPS payment rates. The PHP APCs are converted to a weight relative to the median cost of a Mid-Level Office Visit. The relative weight is multiplied by the conversion factor to convert it to a dollar amount. However, there are other factors in the conversion factor that may offset the market basket increase. For example, the conversion factor includes the wage index and rural budget neutrality adjustments, an adjustment for pass-through set asides, among others. (We refer readers to section X.D of this final rule with comment period for a more detailed discussion of the conversion factor update.)

Comment: One commenter suggested that CMS take a proactive step to prevent the duplication of services by CMHCs by implementing a ''Needs Assessment'' protocol before allowing centers to be established. The commenters stated that these assessments could be used as a way for CMS to determine if the establishment of a CMHC is necessary in a certain area.

Response: We believe the commenter is referring to certificate of need programs implemented by many States, which is beyond the scope of the proposed rule and this final rule with comment period.

Comment: Several commenters expressed concern that cost report data frequently do not reflect bad debt expense for the entire year. The commenters were concerned that these costs are not being considered in the CMS data and severely shortchange the rate calculations.

Response: The bad debt policy is outside the scope of the proposed rule and this final rule with comment period. We refer the commenter to 42 CFR 413.89 and the Provider Reimbursement Manual Part I (PRM), Chapter 3, concerning our bad debt requirements.

Comment: One commenter noted that CMS did not respond to previous statements from commenters that the industry would welcome accreditation rules and/or stricter policies for PHPs.

Response: We agree with the commenters that this is an area that should be addressed, and we are exploring proposing conditions of participation for CMHCs to establish minimum standards for patient rights, physical environment, staffing, and documentation requirements. We believe that adding conditions of participation would contribute to more consistency between CMHCs and hospital-based PHPs.

Comment: One commenter suggested that CMS should consider that licensed professionals with a master's degree in psychology to be equivalent to those with a master's degree in social work with an LCSW. Specifically, the commenter questioned how someone trained in the field to conduct therapy is considered less able than a social worker who may have had minimal or any clinical training.

Response: Specific policy related to the qualification or licensure requirements of mental health professionals is beyond the scope of the proposed rule and this final rule with comment period.

C. Policy Changes

1. Policy To Deny Payment for Low Intensity Days

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66673), we reiterated our expectation that hospitals and CMHCs will provide a comprehensive program consistent with the statutory intent. We also indicated that we intend to explore changes to our regulations and claims processing systems in order to deny payment for low intensity days, and we specifically invited public comment on the most appropriate threshold. We did not receive any public comments on this subject. Our analysis of claims data indicates that CMHCs (and to a lesser extent hospital-based PHPs) are furnishing a substantial number of low unit days. We consider providing only one or two services to be a low unit day. Although we currently consider the acceptable minimum units of PHP services required in a PHP day to be three, it was never our intention that three units of service should represent the number of services to be provided in a typical PHP day. PHP is furnished in lieu of an inpatient psychiatric hospitalization and is intended to be more intensive than a half-day program. We believe the typical PHP day should include five to six units of service with a break for lunch. As indicated in section X.B. of this final rule with comment period, we proposed two PHP per diem rates that reflect the level of care provided.

In conjunction with and to conform to our proposed CY 2009 PHP per diem rates that account for a minimum of 3 units of service provided, we also proposed changes to the existing PHP logic portion of the I/OCE to require that CMHCs and hospital-based PHPs provide a minimum of 3 units of service per day in order to receive PHP payment. Currently, the PHP logic portion of the I/OCE results in a ''suspension of claim for medical review'' for claims with fewer than three services provided in a day. For CY 2009, we proposed to deny payment for any PHP claims for days when fewer than three units of therapeutic services are provided. We believe that three units of services should be the minimum number of services allowed in a PHP day because a day with one or two units of services does not meet the statutory intent of a PHP program. Three units of services are a minimum threshold that permits unforeseen circumstances, such as medical appointments, while allowing payment, but still maintains the integrity of a comprehensive program. As noted previously, we also believe that a day where a patient receives only three units of services should only occur under certain circumstances. As we explained in section X.B. of this final rule with comment period, an example of when it may be appropriate to bill only three units of services a day would be when a patient might need to leave early for a medical appointment and, therefore, would be unable to complete a full day of PHP treatment. However, PHP programs that provide three units of services in a day should be the exception, as we expect PHP programs to generally provide a more intensive day of services as PHP is a more comprehensive program than three units of services. As we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41514), we will be observing trends and assessing the two payment rate approach in our continued review to protect the integrity of the PHP program.

Comment: Commenters supported CMS' proposal to deny payment for ''low unit'' days. However, they stated that CMS should contemplate that there are rare instances when a patient becomes ill or has a family or personal emergency and needs to leave the program early on that day; therefore, they receive fewer services. The commenters suggested that CMS create a modifier to be used to trigger a ''suspension of claim for medical review'' and potential payment at a reduced rate. Other commenters suggested that CMS continue to pay and maintain the current policy of suspending claims for medical review. The commenters believed that this is an appropriate way to make payment determinations. A few other commenters opposed the idea of denying payment; they proposed that CMS pay the fee schedule amount for the one or two services.

Response: While we recognize that special circumstances exist where a patient might have to leave a PHP early, we continue to believe that days with one or two units of services are inconsistent with a benefit designed as a full-day program and substitute for inpatient care. Therefore, we do not believe it is appropriate to establish a modifier at this time or continue to pay and are maintaining the current policy of suspending claims for medical review. In addition, we have codified patient eligibility criteria in this final rule with comment period that will require a minimum of 20 hours of service per week, which strengthens our view that these low intensity days are rare and do not represent a normal day, such that payment should be denied. If there are legitimate instances when one or two units of service days are justified, denial still leaves the provider the option to appeal as specified in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 30, Section 30.2.2. We will continue to monitor data in the future to assess the potential later need for a modifier for such claims.

2. Policy To Strengthen PHP Patient Eligibility Criteria

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66671), we established the current PHP payment rate of $203. As part of our ongoing review of ensuring the most appropriate payment is made for these intensive, service-oriented programs, we also explored changes that could enhance and strengthen the integrity of the PHP benefit overall. As part of this review, we looked at existing instructions to providers, including current regulations, manuals, and other guidance. In the CY 2009 OPPS/ASC proposed rule (73 FR 41514), we proposed to codify existing policy regarding PHP patient eligibility as we believe it will help strengthen the integrity of the PHP benefit by conforming our regulations to our longstanding policy and making available the general program requirements in one regulatory section. These requirements are currently stated in the Medicare Benefit Policy Manual, Pub. 100–02, Chapter 6, section 70.3, available on the CMS Web site at: *http://www.cms.hhs.gov/manuals/Downloads/bp102c06.pdf* and in Transmittal 10, Change Request 3298, dated May 7, 2004, but not codified. The regulatory text changes that we proposed are intended to strengthen PHP requirements by adding the existing patient eligibility conditions to the existing PHP regulations, and do not reflect a change in policy. Specifically, we proposed to revise 42 CFR 410.43 to add a reference to current regulations at § 424.24(e) that requires that PHP services are furnished pursuant to a physician certification and plan of care. While the requirements at § 424.24(e) are not new, we believe the addition of this reference to § 410.43 will provide a more complete description of our expectations for PHP programs in § 410.43.

We also proposed to revise 42 CFR 410.43 to add the following patient eligibility criteria. We proposed to state that partial hospitalization programs are intended for patients who—

(1) Require 20 hours per week of therapeutic services;

(2) Are likely to benefit from a coordinated program of services and

require more than isolated sessions of outpatient treatment;

(3) Do not require 24-hour care;

(4) Have an adequate support system while not actively engaged in the program;

(5) Have a mental health diagnosis;

(6) Are not judged to be dangerous to self or others; and

(7) Have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the partial hospitalization program.

As we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41514), partial hospitalization is the level of intervention that falls between inpatient hospitalization and episodic treatment in the continuum of care for the mentally ill. While we require a patient to have a mental health diagnosis, we caution that the diagnosis in itself is not the sole determining factor for coverage.

Because partial hospitalization is provided in lieu of inpatient care, it should be a highly structured and clinically-intensive program. As reiterated in the CY 2009 OPPS/ASC proposed rule (73 FR 41514), our goal is to improve the level of service furnished in a PHP day, while also ensuring that the partial hospitalization benefit is being utilized by the appropriate population. For example, a PHP candidate should be able to tolerate a day of PHP and benefit from the intense treatment provided in the program. In addition, for the program to be fully beneficial, a PHP participant should have a strong support system outside of the PHP program to help to ensure success. Moreover, the safety of all PHP patients is extremely important and, therefore, all PHP participants should be able to live safely in the community, and not be a danger to self or others. For these reasons, it has been our longstanding policy that these criteria are vital in determining the patient's eligibility to participate in a PHP and we believed it necessary to propose to codify the above list of basic patient eligibility requirements in § 410.43.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66673), we reiterated our expectation that hospitals and CMHCs will provide a comprehensive program consistent with the statutory intent. We believe the addition of these requirements to the regulations reflects our longstanding policy and helps provide a clear and consistent description of our expectations for PHP programs and would strengthen the integrity of the PHP benefit by noting such in the PHP regulations.

Comment: Generally, commenters supported the eligibility requirements and their incorporation in the regulations at § 410.43, with the exception of the requirement that PHPs are intended for patients who require 20 hours per week of therapeutic services. A few commenters requested that CMS clarify that the list of patient eligibility requirements will be used as general requirements or guidelines and not as patient-specific requirements with the potential to deny coverage of services or payments for individual patients. The commenters also indicated that the 20 hours per week requirement, while fundamentally sound, is insufficiently refined for inclusion in regulation and feared the impact of such a strict requirement on patient care. The commenters were concerned that a regulatory provision could result in the denial of coverage for services or payments for individual patients.

Some commenters indicated that a guideline of 16 to 20 hours per week could accommodate the beneficiary, particularly during the transition period following hospital discharge. They stated that partial hospitalization is an intensive form of outpatient care intended for patients with acute psychiatric illness who could benefit from ongoing intensive and structured psychotherapy. The commenters also stated that PHP is frequently used as a substitute or a step-down from hospital care with the patient being transitioned into a less intensive level of care. Other commenters expressed the concern that a patient may not be able to participate at the 20 hour per week minimum for intense therapy, particularly during the transition period. They stated that during the transition, the patient, in addition to psychiatric treatment, frequently needs to make and keep appointments to resolve physical or social issues. A few commenters also indicated that a patient may need an occasional day to acclimate to the rigorous demands of the very intensive level of PHP services. They added that the transition period either before or after hospitalization may frequently warrant clinical discretion and flexibility in patient care management.

Response: We note that the eligibility requirements that we proposed to codify in the regulations at § 410.43 are not new, and are currently a part of the operational policy that is contained in the Medicare Benefits Policy Manual, Pub. 100–02, Chapter 6, Section 70.3.

We understand commenters' concerns about the 20 hours per week requirement with regard to scheduling flexibility, but we are concerned that if we reduce the minimum number of hours lower than the current guideline, the low end of the range will become the new minimum. Therefore, instead of reducing the number of hours a patient needs in order to be eligible to receive the benefit, in this final rule with comment period, we are clarifying that the patient eligibility requirement that patients require 20 hours of therapeutic services is evidenced in a patient's plan of care rather than in the actual hours of therapeutic services a patient receives. The intent of this eligibility requirement is that for most weeks we expect attendance conforming to the patient's plan of care. We recognize that there may be times at the beginning (or end) of a patient's transition into (or out of) a PHP where the patient may not receive 20 hours of therapeutic services. For example, if a patient begins treatment on a Wednesday and receives services for the remainder of that week (Thursday and Friday), that patient's first week may not include 20 hours of therapeutic services. However, we expect that for generally all weeks the PHP patients are receiving the amount and type of services identified in the plan of care.

Therefore, we are finalizing our proposal, with the clarification noted above, the patient eligibility criteria at 42 CFR 410.43 as follows:

Partial hospitalization programs are intended for patients who—

(1) Require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care;

(2) Are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment;

(3) Do not require 24-hour care;

(4) Have an adequate support system while not actively engaged in the program;

(5) Have a mental health diagnosis;

(6) Are not judged to be dangerous to self or others; and

(7) Have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the partial hospitalization program.

We did not receive any public comments on our proposal to revise 42 CFR 410.43 to add a reference to current regulations at § 424.24(e) that requires that PHP services are furnished in accordance with a physician certification and plan of care. Therefore, we are finalizing the cross-reference change as proposed.

3. Partial Hospitalization Coding Update

As part of our ongoing evaluation of partial hospitalization codes, in the CY 2009 OPPS/ASC proposed rule (73 FR

41515), we proposed several coding changes. We identified several CPT codes that we believed were inappropriate for billing PHP claims. Upon further study and after consultation with CMS medical advisors, we proposed to eliminate use of the following three CPT codes for billing PHP claims: 90846 (Family psychotherapy (without the patient present)), 90849 (Multi-family group psychotherapy), and 90899 (Unlisted psychiatric service or procedure). While these three CPT codes constitute 0.157 percent of the total PHP claims for CY 2006, as explained in the CY 2009 OPPS/ASC proposed rule, we believe there are similar and more appropriate HCPCS codes to use to bill for these services.

Our review of the claims data associated with CPT code 90846 found that this code accounts for approximately 0.004 percent of the total services billed on PHP claims in CY 2006. In the CY 2009 OPPS/ASC proposed rule (73 FR 41515) we noted our belief that CPT code 90846 is not an appropriate code for the PHP benefit, because it excludes the beneficiary. We further noted that another available PHP code, CPT code 90847 (Family psychotherapy (conjoint psychotherapy with patient present)), which is currently a billable PHP code, is a more appropriate CPT code to use to bill for family psychotherapy services because it requires the presence of the patient as part of the family psychotherapy session.

In addition, our review of the CY 2006 claims data associated with CPT code 90849 found that this code accounts for approximately 0.058 percent of the total services billed on PHP claims in CY 2006. We also believe that the intended use of this code, which is for the reporting of multiple-family group therapy sessions, is not appropriate for our use under PHP because PHP care is centered on the beneficiary. As stated earlier, we believe that CPT code 90847 is the more appropriate code to use for PHP payment of family psychotherapy services because it provides for the conduct of individualized family psychotherapy with the patient present. Therefore, for CY 2009, we proposed to eliminate CPT code 90849 for use as a PHP code.

In addition, evaluation of the CY 2006 claims data found that CPT code 90899 accounted for approximately 0.095 percent of total services billed on PHP claims. Upon closer examination, we found that CPT code 90899 is predominantly used to bill for patient education services. This is an unlisted CPT procedure code and such CPT unlisted procedure codes are used to report unlisted psychiatric procedures that are not accurately described by any other more specific CPT codes. Because of our concerns about the type of services that may be billed using an unlisted CPT code and because a more appropriate code is currently available that better describes the patient education services for which PHP payment may be made, we proposed to eliminate PHP payment for CPT code 90899 in CY 2009. In the CY 2009 OPPS/ASC proposed rule (73 FR 41515), we further noted that eliminating unlisted CPT procedure codes is consistent with how other payment systems currently treat such codes, in that more specific coding is preferred over general coding.

In addition, we proposed to eliminate two group therapy CPT codes currently used in a PHP setting, 90853 (Group psychotherapy other than of a multiple-family group) and 90857 (Interactive group psychotherapy), and replace them with two new parallel timed HCPCS G-codes: GXXX1 (Group psychotherapy other than of a multiple-family group, in a partial hospitalization setting, approximately 45 to 50 minutes) (now identified as G0410); and GXXX2 (Interactive group psychotherapy, in a partial hospitalization setting, approximately 45 to 50 minutes) (now identified as G0411) (73 FR 41515). As most of the current PHP codes already include time estimates, we indicated in the CY 2009 OPPS/ASC proposed rule that we believe in order to maintain consistency with the existing HCPCS codes used in PHP, the group therapy codes should likewise include a time descriptor. We believe the time of 45 to 50 minutes for a group therapy session is reasonable as it approximately reflects the timing of group sessions in current clinical practices. Therefore, we proposed the two new timed HCPCS G-codes for PHP group therapies. As we noted in the CY 2009 OPPS/ASC proposed rule, both CPT codes 90853 and 90857 may still be used in a non-PHP setting.

Comment: Commenters generally supported the proposed PHP coding changes. Other commenters requested CMS to modify the original proposal and retain a couple of the codes. For example, the commenters agreed with eliminating CPT code 90899 (Unlisted psychiatric service or procedure); they believed removal is reasonable as the code is a generic code and is often misinterpreted by the payer. However, a few commenters opposed the elimination of CPT code 90846 (Family psychotherapy (without the patient present)), and suggested that there are times when family therapy without the patient is highly therapeutic and necessary. The commenters stated discussions with the family on how to handle potential volatile topics with the patient present could have an adverse effect on the patient's behavior.

Some commenters agreed with the removal of CPT code 90849 (Multi-family group psychotherapy). A few other commenters opposed the removal, stating that multigroup psychotherapy is especially beneficial in cases of addiction, as it impacts the entire family. A few commenters requested that CMS not replace the two existing group therapy CPT code 90853 and CPT 90857 with the two new timed G-codes because they believed that using G-codes may create programming and business operational issues and may be administratively burdensome for hospitals. The commenters further believed that the use of G-codes is not consistent with government and industry goals of data uniformity and consistency and, instead, recommended that CMS submit a code proposal to the AMA modifying the two existing group psychotherapy CPT codes 90853 and 90857 by adding the timed elements in their definitions and maintain only one set of codes for these services. Several commenters also believed that the new G-codes' time estimates are inadequate and requested the codes be extended to 60 to 90 minutes.

Response: We appreciate the support of the commenters for removal of CPT code 90899 and, therefore, are finalizing removal of this code from the PHP code set for CY 2009. Although CPT code 90899 will continue to be a billable mental health code, it will no longer be accepted as a PHP billable code. We also appreciate the commenters' support for the use of CPT code 90846 and believe the need for this code in specific clinical situations is valuable. While we remain concerned about therapy that excludes the patient, we agree that this code does have a narrow, although useful, scope. Therefore, CPT code 90846 will remain a billable PHP code. However, we will be monitoring the use of this code to ensure that the frequency of this code does not unduly increase.

We are finalizing the elimination of CPT code 90849 as proposed because we continue to believe that this code is not consistent with the intent of the statute that PHP treatment be focused on the patient's condition. We continue to believe CPT code 90849 focuses the service on the needs of the family and does not specifically focus therapeutic treatment on an individual patient. Therefore, although it will continue to be a billable mental health code, we are

finalizing our policy that CPT code 90849 will no longer be a PHP billable code.

After consideration of the public comments received concerning the creation of the two timed group psychotherapy G-codes, we continue to believe that we have a need to create and maintain G-codes when CPT codes are not available to meet our needs. Moreover, although we generally follow CPT guidelines, there are cases where the CPT system does not meet our payer needs for code specificity, payment and timeliness of assignment, and thus we assign HCPCS codes for those services. We acknowledge that there may be some administrative burden for providers to bill G-codes rather than CPT codes. However, we proposed to establish these two group therapy G-codes because existing CPT group therapy codes do not capture the time component that the proposed G-codes do and, therefore, we continue to believe that creation of G-codes in order to capture timed group psychotherapy visits is necessary. We continue to believe we defined the G-codes according to industry standard for group psychotherapy, allowing for 45 to 50 minutes of therapy with 10 to 15 minutes for documentation. Therefore, we are finalizing the proposed G-codes, with final assigned numbers as follows: G0410 (Group psychotherapy other than of a multiple-family group, in a partial hospitalization setting, approximately 45 to 50 minutes) and G0411 (Interactive group psychotherapy, in a partial hospitalization setting, approximately 45 to 50 minutes).

Lastly, as noted above, while we removed CPT code 90899 from the PHP billable code set, we did not intend to replace it with HCPCS code G0177 (Training and education services related to the care and treatment of patient's disabling mental health problems, per session (45 minutes or more)). HCPCS code G0177 is currently a valid HCPCS code for PHP and will remain a valid HCPCS code for billing patient education and training services in a PHP program. Although HCPCS code G0177 is a packaged code, it is the only valid HCPCS under PHP to bill patient education and training services. It was during data analysis for the CY 2009 OPPS/ASC proposed rule (73 FR 41515) that we observed some providers incorrectly billing patient and education services using CPT code 90899. To clarify, HCPCS code G0177 is the only valid PHP code to bill patient training and education services. We note that HCPCS code G0177 may also be used in a non-PHP setting.

In summary, after consideration of the public comments received, in this final rule with comment period, we are modifying the PHP billable code set to remove CPT codes 90899, 90853, and 90857 for CY 2009. We are retaining CPT code 90846 and adding two new timed G-codes: G0410 (Group psychotherapy other than of a multiple-family group, in a partial hospitalization setting, approximately 45 to 50 minutes) and G0411 (Interactive group psychotherapy in a partial hospitalization setting, approximately 45 to 50 minutes).

The table of billable PHP revenue and HCPCS codes originally published in the April 7, 2000 OPPS final rule with comment period (65 FR 18454) was updated and published in Transmittal 1487, Change Request 5999, dated April 8, 2008, and is currently located in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 4, Section 260.1, which is available on the CMS Web site at: *http://www.cms.hhs.gov/manuals/downloads/clm104c04.pdf.* Table 38 below displays the revised list of billable PHP revenue codes and HCPCS codes shown in Transmittal 1487. This table also includes the four CPT codes that we are removing from the PHP code set for CY 2009 and the two new HCPCS G-codes we are adding to the PHP code set for CY 2009. The four CPT codes that we are removing are shown in the HCPCS code column with a line struck through each code. The two new HCPCS G-codes that we are adding are shown in the HCPCS code column, in the row with revenue code 0915 (Group Therapy). HCPCS code 90846 is shown as retained in the row with revenue code 0916 (Family Psychotherapy).

TABLE 38.--PARTIAL HOSPITALIZATION BILLABLE CODES

Revenue Code	Descriptor	HCPCS Code
043X	Occupational Therapy	G0129
0900	Behavioral Health Treatment/Services	90801 or 90802, ~~*90899*~~
0904	Activity Therapy	G0176
0910	Psychiatric General Services	90801, 90802, 90899 (Dates of Service prior to October 16, 2003)
0914	Individual Psychotherapy	90816, 90817, 90818, 90819, 90821, 90822, 90823, 90824, 90826, 90827, 90828, 90829, 90845, 90865, or 90880
0915	Group Therapy	~~*90849*~~, ~~90853, or 90857~~ G0410 or G0411
0916	Family Psychotherapy	90846 or 90847~~, or *90849*~~
0918	Psychiatric Testing	96101, 96102, 96103, 96116, 96118,96119, or 96120
0942	Education Training	G0177

D. Separate Threshold for Outlier Payments to CMHCs

In the November 7, 2003 final rule with comment period (68 FR 63469), 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. There was a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP. 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. For CYs 2004 and 2005, we designated a portion of the estimated 2.0 percent outlier target amount specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS in each of those years, excluding outlier payments. For CY 2006, we set the estimated outlier target at 1.0 percent and allocated a portion of that 1.0 percent, an amount equal to 0.6 percent (or 0.006 percent of total OPPS payments), to CMHCs for PHP outliers. For CY 2007, we set the estimated outlier target at 1.0 percent and allocated a portion of that 1.0 percent, an amount equal to 0.15 percent of outlier payments (or 0.0015 percent of total OPPS payments), to CMHCs for PHP outliers. For CY 2008, we set the estimated outlier target at 1.0 percent and allocated a portion of that 1.0 percent, an amount equal to 0.02 percent of outlier payments (or 0.0002 percent of total OPPS payments), to CMHCs for PHP outliers. The CY 2008 CMHC outlier threshold is met when the cost of furnishing services by a CMHC exceeds 3.40 times the PHP APC payment amount. The CY 2008 OPPS outlier payment percentage is 50 percent of the amount of costs in excess of the threshold.

The separate outlier threshold for CMHCs became effective January 1, 2004, and 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 final rule with comment period, for CY 2009, we proposed to continue our policy of setting aside 1.0 percent of the aggregate total payments under the OPPS for outlier payments. We proposed that a portion of that 1.0 percent, an amount equal to 0.07 percent of outlier payments (or 0.0007 percent of total OPPS payments), would be allocated to CMHCs for PHP outliers. As discussed in section II.F. of this final rule with comment period, we again proposed 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 did not propose to set a dollar threshold for CMHC outliers. As noted in section II.F. of this final rule with comment period, we proposed to set the outlier threshold for CMHCs for CY 2009 at 3.40 times the APC payment amount and the CY 2009 outlier payment percentage applicable to costs in excess of the threshold at 50 percent.

Comment: A few commenters indicated that they are in favor of eliminating the outlier payments for CMHCs and returning the money in order to possibly increase the base for the PHP payments.

Response: We note that section 1833(t)(5) of the Act requires an outlier policy for covered HOPD services. Partial hospitalization program services are covered HOPD services. Because CMHCs are a provider of PHP services, outlier payments must be provided for them in accordance with the statute. Therefore, until the statute is changed to eliminate the statutory requirement for outlier payments that will affect payment to CMHCs, we are maintaining the current outlier threshold for CMHCs. We would anticipate that if the outlier authority were removed, all OPPS providers, not just CMHCs, would be affected.

As discussed in section II.F of this final rule with comment period, using more recent data for this final rule with comment period, we set the target for hospital outpatient outlier payments at 1.0 percent of total estimated OPPS payments. We allocated a portion of that 1.0 percent, and amount equal to 0.12 percent of outlier payments and 0.0012 percent of total estimated OPPS payments to CMHCs for PHP outliers. For CY 2009, as proposed, we are setting the outlier threshold at 3.40 times the APC amount and CY 2009 outlier percentage applicable to costs in excess of the threshold at 50 percent.

After considering the public comment received, and as noted above, we are finalizing our CY 2009 proposal to set a separate outlier threshold for CMHCs.

XI. 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 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 that are only paid when provided in an 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 (66 FR 59856), we may use any of the following criteria when reviewing procedures to determine whether or not they should be moved from the inpatient list and assigned to an APC group for payment under the OPPS:

- 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:

- We have determined that the procedure is being performed in numerous hospitals on an outpatient basis; or
- We have determined 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.

We believe that these additional criteria help us to identify procedures that are appropriate for removal from the inpatient list.

The list of codes that we proposed to be paid by Medicare in CY 2009 only as inpatient procedures were included as Addendum E to the CY 2009 OPPS/ASC proposed rule.

B. Changes to the Inpatient List

For the CY 2009 OPPS, we used 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. These procedures were then clinically reviewed for possible removal from the inpatient list. As discussed in the CY 2009 OPPS/ASC proposed rule (73 FR 41517), we solicited the APC Panel's input at its March 2008 meeting on the appropriateness of removing the following six CPT codes from the CY 2009 OPPS inpatient list: 21172 (Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)); 21386 (Open treatment of orbital floor blowout fracture; periorbital approach); 21387 (Open treatment of orbital floor blowout fracture; combined approach); 27479 (Arrest, epiphyseal, any method (eg, epiphysiodesis); combined distal femur, proximal tibia and fibula); 54535 (Orchiectomy, radical, for tumor; with abdominal exploration); and 61850 (Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical).

In addition to presenting to the APC Panel the six candidate procedures that we believed could be appropriate for removal from the inpatient list for CY 2009, we also presented utilization data for two procedures, specifically CPT code 64818 (Sympathectomy, lumbar) and CPT code 20660 (Application of cranial tongs caliper, or stereotactic frame, including removal (separate procedure)) that were discussed as possible procedures for removal from the inpatient list during the March 2007 APC Panel meeting. At that meeting, the APC Panel recommended that we obtain additional utilization data for these two procedures for its consideration at the winter 2009 meeting.

Following discussion at the March 2008 APC Panel meeting, the APC Panel recommended that CMS remove from the inpatient list four of the six procedures (presented as candidates for removal from the list), specifically CPT codes 21172, 21386, 21387, and 27479, and one of the two codes for which additional utilization data had been presented, specifically CPT code 20660. The APC Panel also recommended that CMS seek input from relevant physician specialty groups on the removal of two of the six procedures (presented to them as possible candidates for removal from the inpatient list), CPT codes 54535 and 61850. The APC Panel made no recommendation regarding removal of CPT code 64818 from the inpatient list after review of the additional data presented. For CY 2009, we proposed to remove all of the codes except for CPT code 64818 from the inpatient list that were presented to the APC Panel as candidates for removal during its March 2008 meeting and, as recommended by the APC Panel, specifically solicited public comment on the proposed removal of CPT codes 54535 and 61850 from the inpatient list.

In addition to the procedures discussed at the APC Panel's March 2008 meeting, we also reviewed and proposed to remove three procedures from the inpatient list that commenters on the CY 2008 OPPS/ASC proposed rule had requested to be removed. As indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41517), we believe that these procedures are appropriate for removal from the inpatient list and specifically solicited public comment on our proposal to remove the following three procedures: CPT codes 27886 (Amputation, leg, through tibia and fibula; reamputation); 43420 (Closure of esophagostomy or fistula; cervical approach); and 50727 (Revision of urinary-cutaneous anastomosis (any type urostomy)).

Furthermore, during the APC Panel's March 2008 meeting, a meeting attendee requested removal of several CPT codes from the inpatient list. The attendee's verbal request was followed by written correspondence in which the stakeholder requested that we remove five additional procedures from the inpatient list for CY 2009. These procedures were: CPT code 50580 (Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus); CPT code 51845 (Abdomino-vaginal vesical neck suspension, with or without endoscopic control (e.g., Stamey, Raz, modified Pereyra); CPT code 51860 (Cystorrhaphy, suture of bladder wound, injury or rupture; simple); CPT code 54332 (One stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap); and CPT code 54336 (One stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap). Based on our utilization data and clinical review, we proposed to remove one of these procedures from the inpatient list, specifically CPT code 54332, and noted that effective January 1, 2008, CPT code 50580 was removed from the inpatient list and assigned to APC 0161.

At its August 2008 meeting, the APC Panel recommended that we remove three of the procedures that were proposed for removal from the inpatient list, CPT codes 50727, 54332, and 54535, and three additional procedures that were discussed at the meeting in a public presentation. The three additional procedures were CPT codes 51845, 51860, and 54336, codes that were first brought to our attention after the March 2008 APC Panel meeting in the stakeholder letter discussed earlier in this section.

Consistent with our established policy for removing procedures from the inpatient list, we rely on recommendations from the public and the APC Panel, combined with our utilization data and review by CMS medical advisors, to determine which procedures are candidates for removal. We believe that our policy of proposing the procedures for removal and soliciting comments from the public, which includes physician specialty societies, is the most appropriate process to receive input from the public on this issue. Rather than solicit approval from a select group (for example, specific physician specialty societies), we believe that solicitation of comments from all interested parties is more consistent with meeting our obligation to the public regarding outpatient services provided by hospitals. Therefore, as noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41517), we accepted both recommendations of the APC Panel from its March 2008 meeting regarding the inpatient list and (1) proposed to remove the five specific procedures the APC Panel recommended for removal (CPT codes 21172, 21386, 21387, 27479, and 20660) and (2) sought input from relevant professional societies regarding our CY 2009 proposal to remove from the inpatient list CPT codes 54535 and 61850.

Comment: One commenter expressed concerns about the proposed removal of CPT codes 27886 and 54535 from the inpatient list. The commenter stated that there is uncertainty about whether these procedures can be safely performed in an outpatient setting and asked that CMS reconsider the proposed removal of these two procedures. Another commenter supported the proposed removal of CPT code 54535 from the inpatient list.

A few commenters recommended that CMS not remove CPT code 61850 from the inpatient list. One of the

commenters reported that the procedure requires careful observation for hemorrhaging, and expressed the opinion that the procedure should be performed only on an inpatient basis.

Response: Because of the concerns raised by the commenters, we reevaluated CPT codes 27886, 54535, and 61850 in light of the commenters' recommendations combined with our review of updated utilization data and the clinical judgment of our medical advisors. For CPT codes 27886 and 61850, the updated physician billing data for all sites of service indicate that the inpatient utilization for these two CPT codes is higher than their outpatient utilization. In addition, as noted earlier, a commenter has indicated that there is some degree of uncertainty as to whether CPT code 27886 can be performed safely in an outpatient setting. With regard to CPT code 61850, the commenters contended that this procedure cannot be performed safely on an outpatient basis. As stated earlier, one of the commenters indicated that there is a risk of hemorrhaging associated with this procedure. Therefore, based on our reevaluation of CPT codes 27886 and 61850, we agree with the commenters and are not finalizing our proposal to remove these two procedures from the inpatient list for CY 2009.

In reevaluating CPT code 54535 for removal from the inpatient list, we took several additional factors into consideration. First, according to our updated physician billing utilization data, the outpatient utilization for this procedure is somewhat higher than the inpatient utilization. Second, when we presented this procedure to the APC Panel as a possible candidate for removal from the inpatient list at its March 2008 meeting and again at its August 2008 meeting, the APC Panel first requested that we seek stakeholder input on removing CPT code 54535 from the inpatient list at its March meeting and then provided a specific recommendation at its August meeting to remove CPT code 54535 from the inpatient list for CY 2009. Finally, we note that commenters were split in their opinion to remove CPT code 54535 from the inpatient list, with one commenter concerned about the safety of performing this procedure in the outpatient setting while the other commenter supported its removal from the inpatient list. Based on our reevaluation of CPT code 54535, we continue to believe that this procedure can be safely performed in the outpatient setting and we are removing it from the inpatient list for CY 2009.

Comment: One commenter supported CMS' proposal to remove CPT codes 21386 and 21387 from the inpatient list and requested that CMS also remove CPT code 21385 (Open treatment of orbital floor blowout fracture; transantral approach (Caldwell-Luc operation)) from the inpatient list. The commenter pointed out that it was questionable why CMS would propose to remove CPT codes 21386 and 21387 from the inpatient list, but not also remove CPT code 21385 from the inpatient list for CY 2009.

Response: We appreciate the commenter's support for our proposal to remove CPT codes 21386 and 21387 from the CY 2009 inpatient list. We are removing these two procedures from the CY 2009 inpatient list as proposed.

With regard to CPT code 21385, that procedure is not currently on the inpatient list. For CY 2008, CPT code 21385 is assigned to APC 0256 (Level V ENT Procedures). For CY 2009, CPT code 21385 is retained in APC 0256, which we have retitled (Level VI ENT Procedures), and to which CPT codes 21386 and 21387 are assigned.

Comment: One commenter requested that CMS remove CPT code 0184T (Excision of rectal tumor, transanal endoscopic microsurgical approach (i.e., TEMS)) from the inpatient list. The commenter stated that the procedure is minimally invasive and is comparable to CPT code 45170 (Excision of rectal tumor, transanal approach), which is not on the inpatient list.

Response: We consulted with our medical advisors in reevaluating CPT code 0184T for removal from the inpatient list. We note that this CPT code was implemented on January 1, 2008, and was approved by the CPT Editorial Panel in the prior year. When the service was reviewed by the CPT Editorial Panel based on a request for a new CPT code, the procedure was described as requiring a full thickness excision of the rectal wall, with a typical site of service in the inpatient setting and not the HOPD. We have no utilization data for this procedure but, based on the clinical judgment of our medical advisors and the recent deliberations in establishing this new CPT code, we believe that this procedure should remain on the inpatient list.

Comment: One commenter supported CMS' proposal to remove CPT codes 54332 and 50727 from the inpatient list and further recommended that CMS also remove CPT codes 51845, 51860, and 54336 from the inpatient list for CY 2009.

Response: We appreciate the commenter's support. After reevaluating these five CPT codes for payment under the OPPS in CY 2009, we continue to agree that CPT codes 54332 and 50727 can be appropriately performed in the HOPD, consistent with our proposal and the APC Panel's August 2008 recommendation in support of their removal from the inpatient list, and that CPT codes 51845, 51860, and 54336, as recommended by the APC Panel in August 2008, can be safely performed on Medicare beneficiaries in the outpatient setting. Therefore, for CY 2009, we are removing all five of these CPT codes from the inpatient list.

Comment: Many commenters suggested that CMS eliminate the inpatient list and gave several reasons why it should be eliminated. They stated that there was inconsistency between the Medicare payment policies for hospitals and physicians related to performance of inpatient procedures in the HOPD that allows physicians to receive full payment for inpatient procedures that are performed on beneficiaries who are not inpatients but denies hospitals payment for those same procedures. They noted that under, current payment policy, physicians have little incentive to avoid providing inpatient procedures to beneficiaries who are outpatients. The commenters argued that there are a variety of circumstances that result in procedures on the inpatient list being performed without an inpatient admission. For example, they explained that sometimes during the intraoperative period, due to clinical circumstances, the surgeon performs a procedure that is on the inpatient list rather than the procedure that was planned. Further, they asserted that because the inpatient list changes every year, physicians may not always be aware that a particular procedure is on the inpatient list. Finally, some commenters contended that the decision about whether the beneficiary should be an inpatient for surgery should be left to the surgeon and should not be regulated by CMS. They pointed out the many safety provisions that are met by hospitals participating in the Medicare program as evidence that hospitals would provide care safely and appropriately.

Response: We appreciate the comments and understand the commenters' reasons for advocating the elimination of the inpatient list. However, we continue to believe that the inpatient list serves an important purpose in identifying procedures that cannot be safely and effectively provided to Medicare beneficiaries in the HOPD. We are concerned that elimination of the inpatient list could result in unsafe or uncomfortable care

for Medicare beneficiaries. Therefore, we are not discontinuing our use of the inpatient list at this time.

In addition to the above concerns about differences in physician and hospital outpatient payment policy, hospitals have expressed ongoing concerns related to inpatient procedures being performed inappropriately for beneficiaries who are not inpatients and that, as a result, beneficiaries may be liable for the charges for the services. We believe that it is the responsibility of physicians and hospitals to know which procedures are on the inpatient list.

We also are concerned about the potential results of eliminating the inpatient list on beneficiary liability. For instance, we are concerned that, without the inpatient list, beneficiaries could experience longer stays in observation units after some procedures. The APC Panel has discussed its concern with extended time in observation units, frequently exceeding 24 hours. We know that it is not unusual in such cases for the beneficiary to be unaware of his or her outpatient status, which typically means he or she incurs higher out-of-pocket costs. Moreover, the financial liability for OPPS copayments for complex surgical procedures and long periods in the HOPD differs significantly from a beneficiary's inpatient cost-sharing responsibilities.

Comment: In addition to requesting elimination of the inpatient list, a few commenters suggested that if CMS chooses to maintain the list that CMS should establish an appeal process to address those circumstances in which OPPS payment for a service provided on an outpatient basis is denied because it is on the inpatient list. The commenters believed that if CMS maintains the inpatient list that there should be a mechanism by which payment could still be made in some cases. For instance, commenters suggested an appeal process that would allow hospitals to submit information to explain the unusual circumstances that necessitated performance of an inpatient procedure for a beneficiary who is an outpatient.

Response: We appreciate the commenters' suggestions. We intend to continue to encourage physicians' awareness of the implications for beneficiaries and hospitals of performing the inpatient list procedures on beneficiaries who are not inpatients. We do not plan to adopt a specific appeals process for claims related to inpatient list procedures performed in the HOPD at this time. The existing established processes for a beneficiary or provider to appeal a specific claim remain in effect.

Comment: One commenter suggested that CMS implement a method by which the ancillary services related to unscheduled inpatient procedures performed on an outpatient basis could be recognized for payment. The commenter asserted that due to hospital billing practices, hospital coding staff do not know until well after the surgery is complete that an unscheduled inpatient procedure was performed on an outpatient who was not admitted as an inpatient. The commenter requested that CMS create a modifier that hospitals could append to the HCPCS codes for unscheduled inpatient procedures that would enable CMS to recognize and pay for the ancillary services associated with them, comparable to the –CA modifier that addresses 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.

Response: We thank the commenter for the suggestion but do not believe there is a need for a specific modifier to identify unscheduled outpatient performance of inpatient procedures on Medicare beneficiaries. We continue to believe that the inpatient list procedures are not appropriate for performance in the HOPD, and therefore, we expect that when such a procedure is performed on a Medicare beneficiary, the patient would be admitted as an inpatient. We established payment for ancillary services reported in association with an inpatient procedure to which the –CA modifier is appended in order to provide payment to hospitals for services provided in those rare cases when the patient dies before being admitted as an inpatient. In these situations, hospitals are absolutely unable to admit these patients. In the circumstances described by the commenter concerning unscheduled inpatient procedures in the HOPD, we do not believe it would be appropriate to make payment under the OPPS for ancillary services that are provided in association with a procedure that we have designated as only safe for performance on inpatients, and we see no insurmountable hospital barriers to admitting those patients as inpatients of the hospital. We understand hospitals' dilemma when the decision is made intraoperatively to perform an unscheduled procedure. However, we continue to believe that it is very important for hospitals to educate physicians on Medicare services paid under the OPPS to avoid inadvertently providing services in a hospital outpatient setting that would be paid only during an inpatient stay because we believe that the HOPD is not an appropriate site of service for the procedures.

After consideration of the public comments received, we are modifying our CY 2009 proposal to remove 12 CPT codes from the inpatient list. The final list of 12 procedures that we are removing from the inpatient list for CY 2009 is displayed in Table 39 below. The table shows each CPT code and the APC to which the procedure is assigned for OPPS payment in CY 2009. Also, as stated earlier in this section, we will present data regarding CPT codes 20660 and 64818 to the APC Panel at its first CY 2009 meeting. Therefore, in this final rule with comment period, we are accepting the APC Panel's August 2008 recommendation to remove CPT codes 51845, 51860, and 54336 from the inpatient list for CY 2009. We also are accepting the APC Panel's August 2008 recommendation which supported our proposal to remove CPT codes 50727, 54332, and 54535 from the inpatient list for CY 2009.

TABLE 39—HCPCS CODES REMOVED FROM THE INPATIENT LIST AND THEIR APC ASSIGNMENTS FOR CY 2009

CY 2009 HCPCS Code	CY 2009 Long descriptor	Final CY 2009 APC	Final CY 2009 SI
20660	Application of cranial tongs caliper, or stereotactic frame, including removal (separate procedure).	0138	T
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts).	0256	T

TABLE 39—HCPCS CODES REMOVED FROM THE INPATIENT LIST AND THEIR APC ASSIGNMENTS FOR CY 2009—Continued

CY 2009 HCPCS Code	CY 2009 Long descriptor	Final CY 2009 APC	Final CY 2009 SI
21386	Open treatment of orbital floor blowout fracture; periorbital approach.	0256	T
21387	Open treatment of orbital floor blowout fracture; combined approach.	0256	T
27479	Arrest, epiphyseal, any method (eg, epiphysiodesis); combined distal femur proximal tibia and fibula.	0050	T
43420	Closure of esophagostomy or fistula; cervical approach	0254	T
50727	Revision of urinary-cutaneous anastomosis (any type urostomy)	0165	T
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, Stamey, Raz, modified Pereyra).	0202	T
51860	Cystorrhaphy, suture of bladder wound, injury or rupture; simple	0162	T
54332	One stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap.	0181	T
54336	One stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap.	0181	T
54535	Orchiectomy, radical, for tumor; with abdominal exploration	0181	T

XII. OPPS Nonrecurring Technical and Policy Changes and Clarifications

A. Physician Supervision of HOPD Services

In the CY 2009 OPPS/ASC proposed rule (73 FR 41518), we provided a restatement and clarification of the requirements for physician supervision of diagnostic and therapeutic hospital outpatient services that were set forth in the April 7, 2000 OPPS final rule with comment period (65 FR 18524 through 18526).

As we stated before, 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. Section 410.28(e) states that Medicare Part B will make payment for diagnostic services furnished at provider-based departments of hospitals ''only when the diagnostic services are furnished under the appropriate level of physician supervision specified by CMS in accordance with the definitions in §§ 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii).'' In addition, in the April 7, 2000 OPPS final rule with comment period (65 FR 18526), we stated that our model for the requirement was the requirement for physician supervision of diagnostic tests payable under the MPFS that was set forth in the CY 1998 MPFS final rule (62 FR 59048) that was published in the **Federal Register** on October 31, 1998. We also explained with respect to the supervision requirements for individual diagnostic tests that we intended to instruct hospitals and fiscal intermediaries to use the MPFS as a guide pending issuance of updated requirements. For diagnostic services not listed in the MPFS, we stated that fiscal intermediaries, 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 have not subsequently issued new requirements for the physician supervision of diagnostic tests in provider-based departments of hospitals. Instead, we have continued to follow the supervision requirements for individual diagnostic tests as listed in the Physician Fee Schedule Relative Value File. The file is updated quarterly and is available on the CMS Web site at *http://www.cms.hhs.gov/PhysicianFeeSched/.*

Section 1861(s)(2)(B) of the Act authorizes payment for hospital services ''incident to physicians'' services rendered to outpatients.'' We have further defined the requirements for outpatient hospital therapeutic services and supplies ''incident to'' a physician's service in § 410.27 of our regulations. More specifically, § 410.27(f) states, ''Services furnished at a department of a provider, as defined in § 413.65(a)(2) of this subchapter, that has provider-based status in relation to a hospital under § 413.65 of this subchapter, must be under the direct supervision of a physician. 'Direct supervision' means 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.'' This language makes no distinction between on-campus and off-campus provider-based departments.

However, in the preamble of the April 7, 2000 OPPS final rule with comment period (68 FR 18525), we further discussed the requirement for physician supervision and the finalization of the proposed regulation text. In that discussion, we 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 also stated that, for services furnished in a department of a hospital that is located on the campus of a hospital, ''we assume the direct supervision requirement to be met as we explain in section 3112.4(a) of the Intermediary Manual.'' 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.''

As we explained in the CY 2009 OPPS/ASC proposed rule (73 FR 41519), we restated the existing policy because we were concerned that some stakeholders may have misunderstood our use of the term ''assume'' in the April 7, 2000 OPPS final rule with comment period, believing that our statement meant that we do not require any supervision in the hospital or in an on-campus provider-based department for therapeutic OPPS services, or that we only require general supervision for those services. This is not the case. It

has been our expectation that hospital outpatient therapeutic services are provided under the direct supervision of physicians in the hospital and in all provider-based departments of the hospital, specifically both on-campus and off-campus departments of the hospital. The expectation that a physician would always be nearby predates the OPPS and is related to the statutory authority for payment of hospital outpatient services—that Medicare makes payment for hospital outpatient services ''incident to'' the services of physicians in the treatment of patients as described in section 1861(s)(2)(B) of the Act. Longstanding hospital outpatient policy language states that ''the services and supplies must be furnished as an integral though incidental part of the physicians' professional services in the course of treatment of an illness or injury.'' We refer readers to § 410.27(a) of our regulations and to the Medicare Benefit Policy Manual, Pub. 100–2, Chapter 6, Section 20.5.1, for further description of hospital outpatient services incident to a physician's service. The Medicare Benefit Policy Manual also states in Chapter 6, Section 20.5.1, that services and supplies must be furnished on a physician's order and delivered under physician supervision. However, the manual 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.''

The expectation that a physician would always be nearby also dates back to a time when inpatient hospital services provided in a single hospital building represented the majority of hospital payments by Medicare. Since that time, advances in medical technology, changes in the patterns of health care delivery, and changes in the organizational structure of hospitals have led to the development of extensive hospital campuses, sometimes spanning several city blocks, as well as off-campus and satellite provider-based campuses at different locations. In the April 7, 2000 OPPS final rule with comment period (65 FR 18525), we described the focus of the direct physician supervision requirement on off-campus provider-based departments. We will continue to emphasize the physician supervision requirement for off-campus provider-based departments. However, we note that if there were problems with outpatient care in a hospital or in an on-campus provider-based department where direct supervision was not in place (that is, the expectation of direct physician supervision was not met), we would consider that to be a quality concern. We want to ensure that OPPS payment is made for high quality hospital outpatient services provided to beneficiaries in a safe and effective manner and consistent with Medicare requirements.

The definition of direct supervision in § 410.27(f) requires 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. In the April 7, 2000 OPPS final rule with comment period (65 FR 18525), we define ''on the premises of the location'' by stating ''* * * a physician must be present on the premises of the entity accorded status as a department of the hospital and therefore, immediately available to furnish assistance and direction for as long as patients are being treated at the site.'' We also stated that this does not mean that the physician must be physically in the room where a procedure or service is furnished. Although we have not further defined the term ''immediately available'' for this specific context, the lack of timely physician response to a problem in the HOPD would represent a quality concern from our perspective that hospitals should consider in structuring their provision of services in ways that meet the direct physician supervision requirement for HOPD services.

Comment: Several commenters supported the clarification that was provided as a clear and warranted safeguard to individuals being served in on-campus and off-campus departments of hospitals. One commenter was concerned that the restatement and clarification of policy included in the proposed rule would interfere with its ability to provide services in PHP programs and rural CMHCs and stated that ''the current policy is appropriate.'' Another commenter stated that the clarification of policy would cause hospitals to incur significant costs and would result in physician contractual problems and suggested that CMS conduct a study to better understand outpatient settings and the physician supervision currently available to them.

Response: We agree with many of the commenters that appropriate supervision is a key aspect of the delivery of safe and high quality hospital outpatient services to Medicare beneficiaries. As for the concerns of commenters related to hospital staffing and costs, we note that the discussion in the CY 2009 OPPS proposed rule was not a proposed change in policy but was an intended clarification to assist providers who may have misunderstood the policy in the past.

Comment: One commenter requested clarification about whether a nonphysician practitioner can provide supervision of ''incident to'' services in the hospital outpatient setting when the ''incident to service'' is within the practitioner's scope of practice.

Response: According to section 1861(r) of the Act, ''[t]he term 'physician' '', when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action * * *; (2) a doctor of dental surgery or of dental medicine * * *; (3) a doctor of podiatric medicine * * *; (4) a doctor of optometry * * *; or (5) a chiropractor. In addition, the conditions of participation for hospitals under § 482.12(c)(1)(i) through (c)(1)(vi) of our regulations require that every Medicare patient is under the care of a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, a chiropractor, or a clinical psychologist; each practicing within the extent of the Act, the Code of Federal Regulations, and State law. Further, § 482.12(c)(4) of our regulations requires that a doctor of medicine or osteopathy must be responsible for the care of each Medicare patient with respect to any medical or psychiatric condition that is present on admission or develops during hospitalization and is not specifically within the scope of practice of one of the other practitioners listed in § 482.12(c)(1)(ii) through (c)(1)(vi). Also, section 1861(s)(2)(B) of the Act authorizes payment for hospital services ''incident to physicians' '' services rendered to outpatients.'' We have further defined the requirements for outpatient hospital therapeutic services and supplies ''incident to'' a physician's service in § 410.27 of our regulations. Section 410.27(a)(1)(ii) describes payment for hospital outpatient services when they are ''an integral though incidental part of a physician's services.'' Also, § 410.27(f) requires that hospital outpatient services provided in

provider-based departments must be under the direct supervision of a physician. Direct supervision is defined in this paragraph: ''Direct supervision means 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.'' The language of the statute and regulations does not include other nonphysician practitioners. Therefore, it would not be in accordance with the law and regulations for a nonphysician practitioner to be providing the physician supervision in a provider-based department, even if a nurse practitioner's or a physician assistant's professional service was being billed as a nurse practitioner or a physician assistant service and not a physician service.

Comment: One commenter requested clarification of the supervision required for diagnostic services provided in a department of a hospital that is located on the hospital campus.

Response: As explained above, § 410.28(e) of our regulations states that Medicare Part B will make payment for diagnostic services furnished at provider-based departments of hospitals ''only when the diagnostic services are furnished under the appropriate level of physician supervision specified by CMS in accordance with the definitions in §§ 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii).'' We also explained that we have continued to follow the supervision requirements for individual diagnostic tests as listed in the Physician Fee Schedule Relative Value File, updated quarterly and maintained on the CMS Web site as shown above. For diagnostic services not listed in the MPFS, 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. Section 410.28(e) does not distinguish between on-campus and off-campus provider-based departments. Therefore, all provider-based departments providing diagnostic services, whether on or off the hospital's main campus, should follow the requirements of the MPFS or their Medicare contractor, as appropriate, for individual diagnostic services.

Comment: Several commenters provided specific hypothetical scenarios related to the location of the physician and asked whether these situations would meet the definition of direct supervision. One commenter asked for further clarification regarding the supervision level required for specific services.

Response: As stated above and in the CY 2009 OPPS/ASC proposed rule, we require direct supervision for therapeutic services provided in the hospital or in provider-based departments of the hospital. For diagnostic services furnished in provider-based departments, the MPFS level of supervision is applied or the Medicare contractor determines the level of supervision required for services not listed in the MPFS. The definition of direct supervision in § 410.27(f) requires 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. In the April 7, 2000 OPPS final rule with comment period (65 FR 18525), we further clarified that ''on the premises of the location'' means that the physician must be present on the premises of the entity accorded status as a department of the hospital. This means that the physician must be present in the provider-based department. As we explained in the April 7, 2000 final rule with comment period (65 FR 18526), the direct supervision requirement for provider-based departments of hospitals was taken from and parallels the definition of direct supervision in § 410.32(b)(3)(ii), which requires that the physician must be present in the office suite.

Comment: A number of commenters requested that CMS change the level of physician supervision listed in the MPFS for CPT code 77421 (Stereoscopic X-Ray guidance for localization of target volume for the delivery of radiation therapy) from personal supervision to direct supervision.

Response: Changes to supervision requirements for specific CPT codes under the MPFS are outside of the scope of this CY 2009 OPPS/ASC final rule with comment period. We have referred these comments to the appropriate CMS component and would encourage individuals to work with the appropriate specialty society to bring future requests to CMS' attention.

In summary, direct physician supervision is the standard set forth in the April 7, 2000 OPPS final rule with comment period for supervision of hospital outpatient therapeutic services covered and paid by Medicare in hospitals and provider-based departments of hospitals. While we have emphasized and will continue to emphasize the direct supervision requirement for off-campus provider-based departments, we do expect direct physician supervision of all hospital outpatient therapeutic services, regardless of their on-campus or off-campus location. Appropriate supervision is a key aspect of the delivery of safe and high quality hospital outpatient services that are paid based on the statutory authority of the OPPS.

B. Reporting of Pathology Services for Prostate Saturation Biopsy

Prostate saturation biopsy is a technique currently described by Category III CPT code 0137T (Biopsy, prostate, needle, saturation sampling for prostate mapping). Typically this service entails obtaining 40 to 80 core samples from the prostate under general anesthesia. The samples are reviewed by a pathologist, and the pathology service is reported with CPT code 88305 (Level IV—Surgical pathology, gross and microscopic examination). Since the beginning of the OPPS, Medicare has paid for the gross and microscopic pathology examination of prostate biopsy specimens using CPT code 88305. This CPT code has been paid separately under the OPPS and assigned to APC 0343 (Level III Pathology) with status indicator ''X'' since August 2000. For CY 2008, CPT code 88305 is assigned to APC 0343 with a payment rate of approximately $33.

In view of the large number of samples that are taken from a single body organ during prostate saturation biopsy and that must undergo gross and microscopic examination by a pathologist, in the CY 2009 OPPS/ASC proposed rule (73 FR 41519 through 41520), we proposed to recognize four new more specific Level II HCPCS G-codes under the CY 2009 OPPS for these pathology services, consistent with the CY 2009 proposal for the MPFS. The proposed HCPCS codes were: GXXX1 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1–20 specimens); GXXX2 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling 21–40 specimens); GXXX3 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41–60 specimens); and GXXX4 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens). We stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41520), that we believe that the descriptors of these proposed HCPCS G-codes more specifically reflect the

characteristics of prostate saturation biopsy pathology services so that reporting would result in more accurate cost data for OPPS ratesetting and, ultimately, more appropriate payment. CPT code 88305 would continue to be recognized under the OPPS for those surgical pathology services unrelated to prostate needle saturation biopsy sampling. Consistent with the proposed CY 2009 APC assignment for CPT code 88305, we proposed to assign these four new HCPCS G-codes to APC 0343 with a proposed APC median cost of approximately $35. We specifically solicited public comment on the appropriateness of recognizing these proposed new HCPCS G-codes under the OPPS and their proposed APC assignments especially with regard to the expected hospital resources required for the preparation of the biopsy specimens that would be reported with the proposed new HCPCS G-codes and the extent to which those resources necessary to provide a single unit of each proposed new HCPCS G-code would differ from the resources required to provide a single unit of CPT code 88305 for a conventional prostate needle biopsy specimen.

Comment: One commenter opposed the proposal to utilize HCPCS G-codes to report pathology services for prostate saturation biopsy and requested that CMS seek CPT codes for these services in order to avoid coding confusion and the administrative burden of having two code sets for the same service. Another commenter supported the creation of HCPCS G-codes for services involving the examination of more than 21 core samples, but stated that a HCPCS G-code for 20 or fewer samples would be unnecessary and confusing because it would be highly unlikely that a saturation biopsy would be performed to obtain less than 20 specimens. This latter commenter stated that a pathologist would not know whether core samples came from a sextant biopsy versus a saturation biopsy and, therefore, would not know whether to report the proposed HCPCS code GXXX1 or CPT code 88305. The commenter recommended that CPT code 88305 be used for saturation biopsy to report the examination of up to 20 core samples and the following HCPCS G-codes be used to report the examination of more than 20 core samples: GXXX1 (21–40 specimens); GXXX2 (41–60 specimens); and GXXX3 (greater than 60 specimens). The commenter also opposed the proposed assignment of all of the HCPCS G-codes to APC 0343 because the commenter was unclear as to how the proposed payment rate of $35 was calculated. The commenter also believed that CMS did not provide information about whether there would be increased payment for each successive level of specimen samples.

Response: We continue to believe that it is important to pay more appropriately for the pathology services associated with examination of core samples obtained during prostate saturation biopsy. No new CPT codes are being implemented to describe these services for CY 2009. Therefore, we believe that the creation of Level II HPCPCS codes, as we proposed, is essential to providing more appropriate payment for the services in the short term and to collecting claims data that reflect hospitals' costs for the services for future OPPS ratesetting. In contrast to the perspective of one commenter, we believe that, in uncommon cases, prostate saturation biopsy may result in 20 or fewer core samples for examination and that, in such cases, we would expect the hospital resources to differ from the hospital resources required to provide CPT code 88305. Therefore, we are finalizing the creation of the proposed four new more specific Level II HCPCS G-codes under the OPPS for these pathology services, consistent with the CY 2009 final payment policy for the MPFS. As stated in the CY 2009 OPPS/ASC proposed rule (73 FR 41519 through 41520), we believe the proposed descriptors of these HCPCS G-codes more specifically reflect the characteristics of prostate saturation biopsy pathology services so that reporting will result in more accurate cost data for OPPS ratesetting and, ultimately, more appropriate payment.

In considering the commenter's concerns related to the proposed APC assignments for the HCPCS G-codes, we took into account the characteristics of the prostate saturation biopsy pathology services, including typical cases and typical complexity of the pathology review, and we examined the OPPS claims data available for CPT code 88305 and related surgical pathology services. Furthermore, we explicitly assessed the expected incremental hospital resource costs associated with examination of an increasing number of core samples. Based on these analyses and review of the public comments, we concluded that all four HCPCS G-codes are more appropriately assigned to New Technology APCs under the OPPS because there are no established clinical APCs that we believe are appropriate based on consideration of the clinical characteristics and expected hospital resources costs of the services described by the HCPCS G-codes. As discussed further in section III.C. of this final rule with comment period, we maintain new services in New Technology APCs until we have sufficient data to reassign them to appropriate clinical APCs.

After consideration of the public comments received, we are finalizing our CY 2009 proposal to recognize four new HCPCS G-codes for pathology services associated with prostate saturation biopsy, specifically HCPCS codes G0416 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1–20 specimens); G0417 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling 21–40 specimens); G0418 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41–60 specimens); and G0419 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens). CPT code 88305 will continue to be recognized under the OPPS for those surgical pathology services unrelated to prostate saturation biopsy. CPT code 88305 will also continue to be assigned to APC 0343, with a final CY 2009 median cost of approximately $34.

We are not adopting our proposal to assign these four HCPCS G-codes to APC 0343. Instead, in this final rule with comment period, we are assigning these HCPCS G-codes to four different New Technology APCs for CY 2009. For the CY 2009 OPPS, HCPCS code G0416 is assigned to APC 1505 (New Technology—Level V ($300–400)), with a CY 2009 final payment rate of approximately $350; HCPCS code G0417 is assigned to APC 1507 (New Technology—Level VII ($500–600)), with a CY 2009 final payment rate of approximately $550; HCPCS code G0418 is assigned to APC 1511 (New Technology—Level XI ($900–1000)), with a CY 2009 final payment rate of approximately $950; and HCPCS code G0419 is assigned to APC 1513 (New Technology—Level XIII ($1,100–1,200)), with a CY 2009 final payment rate of approximately $1,150. Payment for these services is made at the midpoint of each New Technology APC cost band. Furthermore, each of these New Technology APCs has a status indicator of ''S,'' indicating that there is no discount when multiple significant procedures are provided on the same day to a single Medicare beneficiary. Because the four HCPCS G-codes are new for CY 2009, we are assigning comment indicator ''NI'' in Addendum B to this final rule with comment

period, indicating that their CY 2009 interim OPPS treatment is open to public comment in this final rule with comment period.

C. Changes to the Initial Preventive Physical Examination (IPPE)

In order to implement section 101(b) of the MIPPA, beginning January 1, 2009, we will pay for an IPPE performed not later than 12 months after the date of the beneficiary's initial enrollment in Medicare Part B. Any beneficiary who has not yet had an IPPE and whose initial enrollment in Medicare began in CY 2008 will be able to have an IPPE in CY 2009, as long as it is done within 12 months of the beneficiary's initial enrollment. We will pay for one IPPE for each beneficiary in a lifetime. The Medicare deductible does not apply to the IPPE if it is performed on or after January 1, 2009. Providers paid under the OPPS will report IPPE visits occurring on or after January 1, 2009, using new HCPCS code G0402 (Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment). HCPCS code G0344 (Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 6 months of Medicare enrollment) will be active until December 31, 2008 for beneficiaries who have the IPPE prior to January 1, 2009.

In the CY 2009 OPPS/ASC proposed rule, we proposed to continue the assignment of HCPCS code G0344 to APC 0605 (Level 2 Hospital Clinic Visits) for CY 2009, with a proposed payment rate of approximately $68. We did not receive any public comments on our proposed CY 2009 OPPS treatment of HCPCS code G0344, and therefore, are adopting it as final. We are crosswalking new HCPCS code G0402 to HCPCS code G0344 because of their clinical and expected resource similarity and assigning the new code to APC 0605 on an interim basis for CY 2009. As a new HCPCS code for CY 2009, the OPPS treatment of HCPCS code G0402 is open to public comment in this final rule with comment period. The final CY 2009 median cost of APC 0605 is approximately $67.

We note that the policy for reporting a medically necessary hospital visit during the same visit as the IPPE still applies. CPT codes 99201 through 99215 for hospital clinic visits of new and established patients at all five levels of resource intensity may also be appropriately reported, depending on the circumstances, but they must be appended with the CPT–25 modifier, identifying the hospital visit as a separately identifiable service from the IPPE described by HCPCS code G0402.

Section 101(b) of the MIPPA also removes the screening electrocardiogram (EKG) as a mandatory requirement, as identified in section 1861(ww)(1) of the Act, to be performed as part of the IPPE. The MIPPA requires that there be education, counseling, and referral for an EKG, as appropriate, for a once-in-a lifetime screening EKG performed as a result of a referral from an IPPE. The facility service for the screening EKG (tracing only) is payable under the OPPS when it is the result of a referral from an IPPE. Providers paid under the OPPS should report new HCPCS code G0404 (Electrocardiogram, routine ECG with 12 leads, tracing only, without interpretation and report, performed as a screening for the initial preventive physical examination) for services furnished on or after January 1, 2009. HCPCS code G0367 (Tracing only, without interpretation and report, performed as a component of the initial preventive physical exam) will be active until December 31, 2008 for reporting the facility service for a screening EKG performed prior to January 1, 2009.

In the CY 2009 OPPS/ASC proposed rule, we proposed to continue the assignment of HCPCS code G0367 to APC 0099 (Electrocardiograms) for CY 2009, with a proposed payment rate of approximately $26. We did not receive any public comments on our proposed CY 2009 OPPS treatment of HCPCS code G0367 and, therefore, are adopting it as final. We are crosswalking new HCPCS code G0404 to HCPCS code G0367 because of their clinical and expected resource similarity and assigning the new code to APC 0099 on an interim basis for CY 2009. As a new HCPCS code for CY 2009, the OPPS treatment of HCPCS code G0404 is open to public comment in this final rule with comment period. We note that the two other new related screening EKG codes, specifically HCPCS code G0403 (Electrocardiogram, routine ECG with 12 leads; performed as a screening for the initial preventive physical examination with interpretation and report) and HCPCS code G0405 (Electrocardiogram, routine ECG with 12 leads; interpretation and report only, performed as a screening for the initial preventive physical examination), include an interpretation and report and, therefore, are assigned status indicators ''M'' and ''B,'' respectively, on an interim basis for the CY 2009 OPPS. HCPCS code G0403 and HCPCS code G0405 replace predecessor HCPCS code G0366 (Electrocardiogram, routine ECG with 12 leads; performed as a component of the initial preventive examination with interpretation and report) and HCPCS code G0368 (Interpretation and report only, performed as a component of the initial preventive examination), respectively. Our instructions in the July 2008 OPPS quarterly update, Transmittal 1536, Change Request 6094, issued on June 19, 2008, specify that, in cases where there are separate codes for the technical component, professional component, and/or complete procedure, hospitals paid under the OPPS should report the code that represents the technical component for their facility services. Therefore, hospitals that are billing for HOPD services paid under the OPPS should not report new HCPCS code G0403 or HCPCS code G0405 for payment of the screening EKG under the CY 2009 OPPS, but should instead report new HCPCS code G0404. The final CY 2009 median cost of APC 0099 is approximately $26.

D. Reporting of Wound Care Services

Section 1834(k) of the Act, as added by section 4541 of the BBA, allows payment at 80 percent of the lesser of the actual charge for the services or the applicable fee schedule amount for all outpatient therapy services; that is, physical therapy services, speech-language pathology services, and occupational therapy services. As provided under section 1834(k)(5) of the Act, we created a therapy code list based on a uniform coding system (that is, the HCPCS) to identify and track these outpatient therapy services paid under the MPFS. We provide this list of therapy codes along with their respective designation in the Medicare Claims Processing Manual, Pub 100–04, Chapter 5, Section 20. Two of the designations that we use in that manual denote whether the listed therapy code is an ''always therapy'' service or a ''sometimes therapy'' service. We define an ''always therapy'' service as a service that must be performed by a qualified therapist under a certified therapy plan of care, and a ''sometimes therapy'' service as a service that may be performed by an individual outside of a certified therapy plan of care. We provide payment for several ''sometimes therapy'' wound care services under OPPS if they are provided by the hospital outside of a certified therapy plan of care.

As added to the OPPS via the MPFS process, for CY 2009, CPT code 0183T (Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day) is newly designated as a ''sometimes therapy''

service. In CY 2009, hospitals will receive separate payment under the OPPS when they bill for wound care services described by CPT code 0183T that are furnished to hospital outpatients by individuals independent of a therapy plan of care. In contrast, when such services are performed by a qualified therapist under a certified therapy plan of care, providers should attach an appropriate therapy modifier (that is, ''GP'' for physical therapy, ''GO'' for occupational therapy, and ''GN'' for speech language pathology) or report their charges under a therapy revenue code (that is, revenue codes in the 042x, 043x, or 044x series), or both, to receive payment under the MPFS. For CY 2009, the I/OCE logic assigns this service to APC 0015 (Level III Debridement & Destruction) for payment under the OPPS if the service is not provided under a certified therapy plan of care or directs contractors to pay under the MPFS if the service is identified on a hospital claim with a therapy modifier or therapy revenue code as a therapy service.

E. Standardized Cognitive Performance Testing

Section 1834(k) of the Act, as added by section 4541 of the BBA, essentially establishes that payment for all outpatient therapy services, that is, physical therapy services, speech-language pathology services, and occupational therapy services be provided under a fee schedule. As provided under section 1834(k)(5) of the Act, we created a therapy code list based on a uniform coding system (that is, the HCPCS) to identify and track these outpatient therapy services paid under the MPFS. This list of therapy codes, along with their respective designation, is set forth in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 5, Section 20. Two of the designations that we use in that manual denote whether the listed therapy code is an ''always therapy'' service or a ''sometimes therapy'' service. We define an ''always therapy'' service as a service that must be performed by a qualified therapist under a certified therapy plan of care, and a ''sometimes therapy'' service as a service that may be performed by an individual outside of a certified therapy plan of care.

CPT code 96125 (Standardized cognitive performance testing (eg, Ross Information Processing Assessment) per hour of a qualified health care professional's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report) was a new CPT code effective January 1, 2008, and was assigned status indicator ''A'' in the CY 2008 OPPS/ASC final rule with comment period because it is designated as an ''always'' therapy service under the MPFS. When CPT code 96125 is reported by a hospital, the hospital should attach an appropriate therapy modifier (that is, ''GP'' for physical therapy, ''GO'' for occupational therapy, and ''GN'' for speech language pathology), as noted in the Medicare Claims Processing Manual, Pub. 100–04, Chapter 5, Section 20, and the hospital will receive payment for the service under the MPFS.

Comment: One commenter who addressed our CY 2008 interim assignment of CPT code 96125 asked why this CPT code was assigned status indicator ''A,'' while many other central nervous system assessments and tests were assigned status indicator ''Q'' for the CY 2008 OPPS.

Response: CPT code 96125 is correctly assigned status indicator ''A'' because it is designated as an ''always therapy'' service, as described earlier. The other similar central nervous system assessments and tests are not designated as ''always therapy'' services codes and, therefore, are assigned other appropriate status indicators.

After consideration of the public comment received, we are finalizing the CY 2008 interim assignment of status indicator ''A'' to CPT code 96125 which is designated as an ''always therapy'' service. When reported appropriately by hospitals as a therapy service, CPT code 96125 will be paid under the MPFS.

XIII. OPPS Payment Status and Comment Indicators

A. OPPS Payment Status Indicator Definitions

The OPPS 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 CY 2009 status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this final rule with comment period. As we proposed in the CY 2009 OPPS/ASC proposed rule (73 FR 41520), in this final rule with comment period, we are using the status indicators that were listed in Addendum D1 to the proposed rule, which we discuss below in greater detail. We have made several modifications to the information included in the two columns labeled Item/Code/Service and OPPS Payment Status as displayed in the tables below for this final rule with comment period in response to public comments and to reflect implementation of certain provisions of Public Law 110–275 applicable to services paid under the OPPS in CY 2009.

1. Payment Status Indicators To Designate Services That Are Paid under the OPPS

We proposed several changes to these status indicators for the CY 2009 OPPS, and the Item/Code/Service and OPPS Payment Status columns listed in the table below reflect further modifications based on the provisions of Public Law 110–275 for CY 2009.

Indicator	Item/code/service	OPPS Payment status
G	Pass-Through Drugs and Biologicals	(1) Paid under OPPS; separate APC payment.
H	(1) Pass-Through Device Categories	(1) Separate cost-based pass-through payment; not subject to copayment.
	(2) Therapeutic Radiopharmaceuticals	(2) Separate cost-based nonpass-through payment; subject to copayment.
K	Nonpass-Through Drugs and Biologicals	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.

Indicator	Item/code/service	OPPS Payment status
		(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.
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.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41521), we proposed to replace current status indicator ''Q'' with three new separate status indicators: ''Q1,'' ''Q2,'' and ''Q3'' for CY 2009. We proposed that status indicator ''Q1'' would be assigned to all ''STVX-packaged codes,'' status indicator ''Q2'' would be assigned to all ''T-packaged codes;'' and status indicator ''Q3'' would be assigned to all codes that may be paid through a composite APC based on composite-specific criteria or separately through single code APCs when the criteria are not met. We believe this proposed change to establish new status indicators ''Q1,'' ''Q2,'' and ''Q3'' would make our policies more transparent to hospitals and would facilitate the use of status indicator-driven logic in our ratesetting calculations, and in hospital billing and accounting systems.

For CY 2009, we also proposed to use new payment status indicator ''R'' for all blood and blood product APCs and to use new payment status indicator ''U'' for brachytherapy source APCs. Nonpass-through drugs and biologicals which do not require a conversion factor to calculate their payment rates would continue to be assigned status indicator ''K.'' We proposed to create these new status indicators for blood and blood products and for brachytherapy sources to facilitate implementation of the reduced conversion factor that would apply to payments to hospitals that are required to report quality data but that fail to meet the established quality data reporting standards.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41521), we noted our belief that this proposal was necessary to continue the final CY 2008 policies of setting prospective payment rates for brachytherapy sources and blood and blood products calculated as the product of scaled relative weights and the conversion factor. Under our CY 2009 proposal, payment for blood and blood products and brachytherapy sources would have been subject to the reduced market basket conversion factor for hospitals that failed to meet the requirements of the HOP QDRP, while separately payable nonpass-through drugs and biologicals would not have been paid based on the conversion factor. We would have been unable to use status indicator ''K'' alone to indicate application of the reduced conversion factor to payment for the appropriate products if we continued to assign status indicator ''K'' to all of these items. Section XVI. of this final rule with comment period provides a full discussion of the requirements of the HOP QRDP and the reduced market basket conversion factor that will apply to payment for specific services when hospitals for which the reporting is required fail to meet the reporting standards.

Subsequent to issuance of the CY 2009 OPPS/ASC proposed rule, Public Law 110–275 was enacted on July 15, 2008. Section 142 of Public Law 110–275 requires CMS to continue to pay for brachytherapy sources and therapeutic radiopharmaceuticals for the period of July 1, 2008 through December 31, 2009, at hospitals' charges adjusted to the costs, a methodology that is different from the approaches we proposed for these items in CY 2009. We have continued to assign status indicator ''H'' to brachytherapy sources for July 1, 2008 through December 1, 2008, to ensure appropriate payment for these items. Moreover, we are not adopting the proposed prospective payment for brachytherapy sources and therapeutic radiopharmaceuticals, and we are not assigning status indicator ''K'' to therapeutic radiopharmaceuticals for CY 2009, as proposed. For this final rule with comment period, we have modified our proposed definition of status indicator ''K'' to include only nonpass-through drugs and biologicals and, in parallel fashion, we have modified our proposed definition of status indicator ''H'' to include therapeutic radiopharmaceuticals for CY 2009. We note that beneficiary copayment does apply to payment for therapeutic radiopharmaceuticals assigned status indicator ''H,'' although pass-through device category, also assigned status indicator ''H,'' will continue to have no beneficiary copayment applied. The national unadjusted copayment or minimum

unadjusted copayment, as applicable, applies to all APC payments for OPPS services unless there is a statutory exception. There is no statutory exception for payment of therapeutic radiopharmaceuticals and, therefore, copayment applies to these products in CY 2009. However, where additional pass-through payment is made for a device category or drug that has pass-through status, section 1833(t)(8)(E) of the Act requires that the copayment for the device category or drug furnished be calculated as though the additional pass-through payment had not been made. Therefore, there is no copayment for the additional pass-through payment for a device category with OPPS pass-through status. The OPPS PRICER would continue to ensure that no copayment would be assigned for pass-through device categories that may be approved for CY 2009.

CY 2009 payment for therapeutic radiopharmaceuticals, to which the reduced market basket conversion factor does not apply, is discussed in detail in section V.B.4. of this final rule with comment period. The payment methodology for brachytherapy sources specified by section 142 of Public Law 110–275 requires no changes to our proposed definition of status indicator ''U'' for brachytherapy sources because the definition only indicated that separate payment would be made, without specifying the payment methodology. CY 2009 payment for brachytherapy sources, to which the reduced market basket conversion factor does not apply, is discussed in detail in section VII. of this final rule with comment period.

Comment: Several commenters supported the proposed assignment of a separate status indicator to blood and blood products and encouraged CMS to make status indicator ''R'' final.

Response: We appreciate the commenters' support of status indicator ''R.'' New status indicator ''R'' for blood and blood products was created in order to facilitate implementation of the reduced market basket conversion factor that applies to payments to hospitals that are required to report quality data but fail to meet the established quality reporting standards. This reduced conversion factor applies to CY 2009 payment for blood and blood products, as further discussed in section XVI.D.2. of this final rule with comment period.

Comment: Several commenters supported the proposal to refine status indicator ''Q'' by creating three related status indicators: ''Q1,'' ''Q2,'' and ''Q3.'' These commenters stated that these changes would allow providers to quickly and easily isolate HCPCS codes that are packaged for different reasons. Commenters believed that the creation of status indicators ''Q1,'' ''Q2,'' and ''Q3'' make the conditionally packaged payment policy for each HCPCS code more transparent and urged CMS to finalize this proposal.

Response: We appreciate the commenters' support regarding the development and use of status indicators ''Q1,'' ''Q2,'' and ''Q3'' to identify different types of conditionally packaged services. We continue to believe that these refinements are helpful in identifying the packaging rationale for different HCPCS codes under the OPPS.

After consideration of the public comments received, we are finalizing our CY 2009 proposal for status indicators to designate services payable under the OPPS, with modification to take into consideration provisions of Public Law 110–275 for CY 2009. The final status indicators and their descriptions are displayed in the table above, as well as in Addendum D1 to this final rule with comment period.

2. Payment Status Indicators To Designate Services That Are Paid Under a Payment System Other Than the OPPS

We did not propose any changes to the status indicators as listed below for the CY 2009 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.
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.

We did not receive any public comments regarding the status indicators that designate services paid under a payment system other than the OPPS. Therefore, we are finalizing our CY 2009 proposal, without modification. The final status indicators are displayed in the table above, as well as in Addendum D1 to this final rule with comment period.

3. Payment Status Indicators To Designate Services That Are Not Recognized Under the OPPS But That May Be Recognized by Other Institutional Providers

We did not propose any changes to the status indicators listed below for the CY 2009 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.

We did not receive any public comments regarding the status indicators that designate services that are not recognized under the OPPS but that may be recognized for payment to other institutional providers. Therefore, we are finalizing our CY 2009 proposal, without modification. The final status indicators are displayed in the table above, as well as in Addendum D1 to this final rule with comment period.

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

We did not propose any changes to these status indicators for the CY 2009 OPPS, but the Item/code/service and OPPS Payment status columns for status indicator ''E'' listed in this table below reflect modifications in response to public comments.

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: • 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.	Not paid by Medicare when submitted on outpatient claims (any outpatient bill type).

Comment: Several commenters observed that as the Medicare program has evolved to incorporate other benefits, such as payment for prescription drugs under Medicare Part D, the historical definition of status indicator ''E,'' specifically that these items and services are not paid under the OPPS or any other Medicare payment system, is no longer accurate.

Response: We appreciate the commenters' concern and have clarified the definition of status indicator ''E'' in the table above to indicate more precisely that status indicator ''E'' designates items and services that are not payable when submitted on outpatient claims of any bill type. We have also clarified that these items and services are not covered by the Medicare outpatient benefit, in recognition that they may be covered under some circumstances under other benefits of the Medicare program.

After consideration of the public comments received, we are finalizing our CY 2009 proposal for payment status indicators to designate services that are not payable by Medicare for outpatient claims, with modification to clarify that status indicator ''E'' indicates no payment for outpatient claims, rather than no payment under any Medicare benefit. The final status indicators are displayed in the table above, as well as in Addendum D1 to this final rule with comment period.

To address providers' broader interests and to make the published Addendum B more convenient for public use, we are displaying in Addendum B to this final rule with comment period all active HCPCS codes for CY 2009 and currently active HCPCS codes that will be discontinued at the end of CY 2008 that describe items and services that are: (1) Payable under the OPPS; (2) paid under a payment system other than the OPPS; (3) not recognized under the OPPS but that may be recognized by other institutional providers; and (4) not payable by Medicare. The universe of CY 2009 status indicators that we are finalizing for these items and services are listed in the tables above and in Addendum D1 to this final rule with comment period.

Addendum B, with a complete listing of HCPCS codes that includes their payment status indicators and APC assignments for CY 2009, is available electronically on the CMS Web site under supporting documentation for this final rule with comment period at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/list.asp#TopOfPage*

B. Comment Indicator Definitions

In the CY 2009 OPPS/ASC proposed rule (73 FR 41522), we proposed to use for the CY 2009 OPPS the two comment indicators that are in effect for the CY 2008 OPPS. These two comment indicators are listed below.

- ''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, interim APC assignment; Comments will be accepted on the interim APC assignment for the new code.

Except as discussed below with regard to services to which we have assigned status indicators ''R,'' ''Q1,'' ''Q2,'' ''Q3,'' and ''U,'' we proposed to use the ''CH'' comment indicator in this

final rule with comment period to indicate HCPCS codes for which the status indicator or APC assignment, or both, will change in CY 2009 compared to their assignment as of December 31, 2008.

As was proposed, we are using the ''CH'' indicator in this CY 2009 OPPS/ASC final rule with comment period to call attention to changes in the payment status indicator and/or APC assignment for HCPCS codes for CY 2009 compared to their assignment as of December 31, 2008. We believe that use of the ''CH'' indicator in the CY 2009 OPPS/ASC final rule with comment period will facilitate the public's review of the changes that we are finalizing for CY 2009. The use of the comment indicator ''CH'' in association with a composite APC indicates that the configuration of the composite APC is changed in this CY 2009 OPPS/ASC final rule with comment period.

''STVX-packaged codes,'' ''T-packaged codes,'' and other HCPCS codes that could be paid through a composite APC with final CY 2009 changes in status indicator assignments from ''Q'' to ''Q1,'' from ''Q'' to ''Q2,'' and from ''Q'' to ''Q3,'' as well as HCPCS codes for blood and blood products and for brachytherapy sources with final CY 2009 changes in status indicator assignments from ''K'' to ''R'' and from ''H'' to ''U,'' respectively, are not flagged with comment indicator ''CH'' in Addendum B to this final rule with comment period. As noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41522), these changes in status indicators are to facilitate policy transparency and operational logic rather than to reflect changes in OPPS payment policy for these services, so we believe that identifying these HCPCS codes with ''CH'' could be confusing to the public.

As was proposed, we are continuing our policy of using comment indicator ''NI'' in this CY 2009 OPPS/ASC final rule with comment period. Only HCPCS codes with comment indicator ''NI'' in this CY 2009 OPPS/ASC final rule with comment period are subject to comment. HCPCS codes that do not appear with comment indicator ''NI'' in this CY 2009 OPPS/ASC final rule with comment period are not open to public comment, unless we specifically have requested additional comments elsewhere in this final rule with comment period. The CY 2009 treatment of HCPCS codes that appear in this CY 2009 OPPS/ASC final rule with comment period to which comment indicator ''NI'' is not appended was open to public comment during the comment period for the CY 2009 OPPS/ASC proposed rule, and we are responding to those comments in this final rule with comment period.

We did not receive any public comments regarding comment indicators. Therefore, we are continuing to use the two comment indicators, ''CH'' and ''NI,'' for CY 2009 and their definitions are listed in Addendum D2 to this final rule with comment period.

XIV. OPPS Policy and Payment Recommendations

A. Medicare Payment Advisory Commission (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 present its Medicare payment policy recommendations. The following section describes recent recommendations relevant to the OPPS that have been made by MedPAC.

1. March 2008 Report

The March 2008 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 2009 by the projected rate of increase in the hospital market basket index, concurrent with implementation of a quality incentive payment program.

CMS Response: As proposed in the CY 2009 OPPS/ASC proposed rule (73 FR 41457), in this final rule with comment period we are increasing the payment rates for the CY 2009 OPPS by the projected rate of increase in the hospital market basket through adjustment of the full CY 2009 conversion factor. We also are implementing, effective for CY 2009, the reduction in 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, as added by section 109(a) of the MIEA–TRHCA (Pub. L. 109–432). Specifically, we have calculated two conversion factors: A full conversion factor based on the full hospital market basket increase and a reduced conversion factor that reflects the 2.0 percentage point reduction to the market basket. Our update of the conversion factor and our adoption and implementation of the reduced conversion factor that will apply to hospitals that fail their quality reporting requirements for the CY 2009 OPPS are discussed in detail in section XVI.D.2. of this final rule with comment period.

This full MedPAC report can be downloaded from MedPAC's Web site at: *http://www.medpac.gov/documents/Mar08_EntireReport.pdf*.

2. June 2007 Report

In its June 2007 ''Report to the Congress: Promoting Greater Efficiency in Medicare,'' MedPAC included analysis and recommendations on alternatives to the current method for computing the IPPS wage index for FY 2009. (We refer readers to Chapter 6 of the June 2007 MedPAC report to Congress.) In accordance with our established policy, under the OPPS we adopt the IPPS wage indices to adjust the OPPS standard payment amounts for labor market differences. Therefore, MedPAC's analysis and recommendations have implications for the CY 2009 OPPS. We considered MedPAC's recommendations and analysis in making a proposal to revise the IPPS wage indices in the FY 2009 IPPS proposed rule (73 FR 23617 through 23623), as required by section 106(b)(2) of the MIEA–TRHCA, and we briefly highlighted the CMS contractor's comparative and impact analyses of the MedPAC and CMS wage indices and the public comments received regarding the recommendations in the FY 2009 IPPS final rule (73 FR 48564 through 48567). In section II.C. of this final rule with comment period, we discuss changes to the wage index related to the MedPAC recommendations that were adopted in the FY 2009 IPPS final rule and our application of these changes to the wage index for the CY 2009 OPPS.

This full MedPAC report can be downloaded from MedPAC's Web site at: *http://www.medpac.gov/documents/Jun07_EntireReport.pdf*.

B. APC Panel Recommendations

Recommendations made by the APC Panel at its March 2008 and August 2008 meetings are discussed in sections of this final rule with comment period that correspond to topics addressed by the APC Panel. The report and recommendations from the APC Panel's March 5–6, 2008 and August 27–28, 2008 meetings are available on the CMS Web site at: *http://www.cms.hhs.gov/FACA/05_AdvisoryPanelonAmbulatoryPaymentClassificationGroups.asp.*

C. OIG Recommendations

The mission of the OIG, as mandated by Public Law 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. In June 2007, the OIG released a report, entitled ''Impact of Not Retroactively Adjusting Outpatient Outlier Payments,'' that described the OIG's research into sources of error in CMHC outlier payments. The OIG report included the following two recommendations related specifically to the hospital OPPS under which payment is made for outpatient services provided by CMHCs.

Recommendation 1: The OIG recommended that CMS require adjustments of outpatient outlier payments at final cost report settlement, retroactive to the beginning of the cost report period.

CMS Response: We have been proactive in addressing this issue for partial hospitalization prospective payment by designating a unique outlier threshold for CMHCs beginning in CY 2004. As discussed in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68002 through 68003), differences in total CMHC outlier payments between CY 2004 and CY 2005 demonstrate that designating a separate threshold has successfully restrained CMHC outlier payments. Moreover, until the CY 2005 implementation of a fixed-dollar outlier threshold for most other hospital outpatient services that concentrates outlier payments on costly and complex services, we did not believe it would be cost-effective to pursue adjustments of outlier payments for all of the OPPS. However, in addition to the unique outlier threshold for CMHCs that we have recently adopted to address excessive CMHC outlier payments, we proposed to provide for reconciliation of outlier payments under the OPPS at final cost report settlement as recommended by the OIG, beginning in CY 2009. We discuss our final policy to reconcile outlier payments, beginning in CY 2009, in more detail in section II.F.3. of this final rule with comment period.

Recommendation 2: The OIG recommended that CMS require retroactive adjustments of outpatient outlier payments when an error caused by the fiscal intermediary or provider is identified after the cost report is settled.

CMS Response: We note that the OIG's findings were based largely on information from the OPPS' early implementation period, between CY 2000 and CY 2003. We believe we have taken several steps since that time in order to improve the accuracy and frequency of the Medicare contractors' CCR calculations, including updating our instructions for calculating CCRs, increasing the frequency of CCR calculation, and conducting an annual review of CMHC CCRs. However, in light of this OIG recommendation, for the CY 2009 OPPS, we also proposed to provide for reconciliation of outlier payments under the OPPS. We discuss our final policy to reconcile outlier payments in more detail in section II.F.3. of this final rule with comment period.

XV. Ambulatory Surgical Centers: Updates and Revisions to the Ambulatory Surgical Center Conditions for Coverage and Updates to the Revised Ambulatory Surgical Center Payment System

A. Legislative and Regulatory Authority for the ASC Conditions for Coverage

As the single largest payer for health care services in the United States, the Federal Government assumes a critical responsibility for the quality of care furnished under its programs. Historically, the Medicare program's quality assurance approach was focused on identifying health care entities that furnished poor quality care or that failed to meet minimum Federal standards. Overall, we found that this problem-focused approach had inherent limitations and did not necessarily translate into better care for patients. Ensuring quality through the enforcement of prescriptive health and safety standards alone has resulted in us expending many of our resources on working with marginal providers, rather than stimulating broad-based improvements in quality of care.

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 ASC. To participate in the Medicare program as an ASC, a facility must meet health, safety, and other requirements under the statutory authority of section 1832(a)(2)(F)(i) of the Act. The substantive requirements 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 42 CFR Part 416, Subpart C specify the conditions for coverage (CfCs) for ASCs. The Secretary is responsible for ensuring that the CfCs and their enforcement are adequate to protect the health and safety of individuals treated by ASCs.

To implement the CfCs, we determine compliance through State survey agencies or accreditation organizations that conduct onsite inspections utilizing these requirements. In order to participate in the Medicare program, ASCs must meet Medicare standards as determined by a State agency or by a national accrediting organization approved by the Secretary and whose standards meet or exceed the CfCs. Currently, there are four national accreditation organizations that are approved by the Secretary:

- The Joint Commission;
- The American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF);
- The Accreditation Association for Ambulatory Health Care (AAAHC); and
- The American Osteopathic Association (AOA).

With respect to payment for surgical procedures performed in a Medicare-certified ASC, there are two primary elements to the total cost of performing a surgical procedure: (a) The cost of the physician's professional services to perform the procedure; and (b) the cost of items and services furnished by the facility where the procedure is performed (for example, surgical supplies, equipment, and nursing services). Payment for the first element is made under the Medicare Physician Fee Schedule (MPFS). We address the second element, payment for the cost of items and services furnished by the facility, in sections XV.C. through XV.F. of this document.

B. Updates and Revisions to the ASC Conditions for Coverage

1. Background

On August 31, 2007, we published a proposed rule in the **Federal Register** entitled ''Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage'' (72 FR 50470). In that proposed rule, we proposed to revise the definitions of certain terms used in the ASC CfCs set forth in § 416.2 and some of the existing specific CfCs pertaining to the ASC governing body and management, evaluation of quality, and laboratory and radiologic services, which are set forth in §§ 416.41, 416.43, and 416.49, respectively, to reflect current ASC practices. In addition, we proposed to add several new CfCs on patient rights, infection control, and patient admission, assessment, and discharge to promote and protect patient health and safety.

The current ASC CfCs were originally published on August 5, 1982 (47 FR

34082), and, for the most part, these regulations have remained unchanged since that time. From 1990 to 2000, the number of ASCs participating in the Medicare program has increased at a rate of about 175 facilities a year. The total number of ASCs more than doubled from 1,197 to 2,966 during this 10-year period, making ASCs one of the fastest growing facility types in the Medicare program. The annual volume of procedures performed on both Medicare and non-Medicare patients has tripled.

Currently, over 5,100 ASCs participate in the Medicare program.[1] This growth is due in part to advances in medical technology that allow additional surgical procedures to be safely performed outside of a hospital setting. This shift has paved the way for increasing numbers of procedures to be performed in an ASC. The changes we proposed are more aligned with today's ASC health care industry standards.

In addition, HHS' health care information transparency initiative (discussed more fully in the CY 2007 OPPS/ASC final rule with comment period (71 FR 67960)) gives consumers what we believe to be accessible and useful information on the price and quality of health care items and services so that they can more meaningfully exercise choices in selecting health care. In support of this initiative, in August 2006, we announced the release of Medicare payment information for 61 procedures performed in ASCs. This information is available on the CMS Web site at: *http://www.cms.hhs.gov/HealthCareConInit/* and will assist patients undergoing surgical procedures to select the most appropriate setting for the delivery of high quality, efficient care. The information shows ''Commonly Performed Procedures in ASCs'' and contains ASC charges and Medicare payment data for ASC facility costs for a limited number of services administered in States and counties. The data are broken down at the county, State, and national level. Moreover, the CMS Web site at *http://www.cms.hhs.gov/center/ombudsman.asp* is available to the public and ASC patients to get information about the Medicare and Medicaid programs, prescription drug coverage, and how to coordinate Medicare benefits with other health insurance programs. The Web site also includes information about filing a grievance or complaint.

Section 109(b) of the MEIA–TRHCA (Pub. L. 109–432) amended section 1833(i) of the Act to authorize the Secretary to develop measures that are appropriate to determine the measurement of quality care (including medication errors) furnished by ASCs that reflect the consensus among affected parties and to reduce the annual payment update by 2 percentage points for any ASC that does not submit data on quality measures in the form and manner required by the Secretary. These measures, to the extent feasible and practicable, must include measures set forth by one or more national consensus building entities (section 1833(t)(17)(C) of the Act). We refer readers to section XVI.H. of this rule for a more detailed discussion of these measures. We expect Medicare beneficiaries to receive high quality surgical services and, for that reason, we proposed a Quality Assessment Performance Improvement (QAPI) requirement as a new condition for coverage (§ 416.43). (We refer readers to section XV.B.2.b.(2) of this final rule for a more detailed discussion of the QAPI provision.)

2. Provisions of the Proposed and Final Regulations

As stated earlier, the ASC CfCs were originally issued in 1982. Most of the revisions made since then have been payment-related. Since 1982, significant innovations in ASC patient care delivery and quality assessment practices have emerged. In an effort to ensure continued quality in the ASC setting, in the 2007 ASC CfCs proposed rule, we proposed to revise three of the existing conditions and create three new conditions. The proposed revised conditions are: Governing body and management; Evaluation of quality (renamed Quality Assessment and Performance Improvement (QAPI)); and Laboratory and radiologic services. The proposed new conditions are: Patient rights; Infection control, and Patient admission, assessment, and discharge. As stated in the 2007 ASC CfCs proposed rule (72 FR 50470), our objective is to achieve a balanced regulatory approach by ensuring that an ASC furnishes health care to meet essential health and quality standards, while ensuring that it monitors and improves its own performance.

In this section, we discuss the revised and new ASC requirements that we proposed, summarize the public comments received, present our responses, and set forth our final policies.

a. Definitions (§ 416.2)

Existing § 416.2 sets forth definitions for terms used in the ASC CfCs. We proposed to revise the definition of ''Ambulatory surgical center'' or ''ASC.'' In addition, we proposed to add a definition for ''overnight stay'' to § 416.2.

We proposed to revise the ASC definition to read as follows:

Ambulatory surgical center or *ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring an overnight stay following the surgical services, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part [416].

We proposed to revise the overnight stay definition to read as follows:

Overnight stay means the patient's recovery requires active monitoring by qualified medical personnel, regardless of whether it is provided in the ASC, beyond 11:59 p.m. of the day on which the surgical procedure was performed.

In the Medicare cost reporting manual (Provider Reimbursement Manual, Part 1, Section 2205 (Medicare Patient Days, page 22–16)), we have defined a hospital inpatient day as beginning at midnight and ending 24 hours later. Consistent with this longstanding policy, we proposed to codify in regulations that any patient whose recovery requires active monitoring by qualified personnel beyond 11:59 p.m. of the day on which the surgical procedure was performed, is a patient who may require hospitalization or more intensive care. Accordingly, we proposed that ASCs that are Medicare-certified may not keep patients beyond 11:59 p.m. of the day on which the surgical procedure was performed.

In the August 2, 2007 final rule that established the revised ASC payment system (72 FR 42546), we added in new § 416.166(b) that covered surgical procedures ''would not typically be expected to require active medical monitoring and care at midnight following the procedure.'' In the CY 2007 OPPS/ASC proposed rule and CY 2007 OPPS/ASC final rule with comment period (71 FR 49639 and 71 FR 68168, respectively), we addressed the denial of payment of an ASC facility fee for any procedure for which prevailing medical practice dictated that the beneficiary would typically be expected to require active medical monitoring and care at midnight following the procedure. We also note that the patient's location at midnight was a generally accepted standard for

[1] Only comprehensive rehabilitation facilities and rural health clinics have experienced a higher rate of growth. Office of Evaluations and Inspections (OEI) analysis of Part B Medicare data. See Office of Inspector General Quality Oversight of Ambulatory Surgical Centers Supplemental Report 1: The Role of Certification and Accreditation.

determining his or her status as a hospital inpatient or SNF patient and, as such, it is reasonable to apply the same standard in the ASC setting.

Comment: Many commenters suggested that CMS keep the current ASC definition as it is currently written. The commenters believed the proposed definition was too restrictive. Other commenters noted that some ASCs operate on a 24-hour basis and that the 11:59 p.m. cutoff time was not in keeping with current practice.

Response: After consideration of the public comments received, we are not finalizing the proposed definition of ''overnight stay'' and have revised the proposed definition of ''ASC'' to recognize that the hours of operation of an ASC have an impact on patient discharge schedules. In this final rule, we have defined ''ASC'' to mean a ''distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed twenty-four hours following admission. The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in subparts B and C of this part [416].''

Patients admitted to an ASC will be allowed to stay in the facility for 23 hours and 59 minutes starting at the time of admission. This policy will create a 24-hour rolling clock that will allow ASCs the flexibility to perform procedures later in the day or to perform those procedures that require more lengthy patient recovery times.

In summary, we are finalizing our proposal, with modification, to revise the definition of ''ASC'' at § 416.2 to state that an ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to ''patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission,'' instead of ''patients not requiring an overnight stay following the surgical services,'' as proposed. There may be rare instances when a Medicare patient is required to stay beyond 24 hours due to an unexpected result from a surgery that would require further monitoring and care. Such a stay would be unplanned and the ASC would continue to be responsible for the patient and provide care until the patient is stable and able to be discharged in accordance with the ASC regulations and facility policy.

b. Specific Conditions for Coverage

(1) Condition for Coverage: Governing Body and Management (§ 416.41)

The proposed Governing body and management CfC was separated into three standards to more clearly articulate CMS expectations. We also proposed two new items: First, the governing body would have oversight and be accountable for the quality assessment and performance improvement program; and second, the ASC would be expected to maintain a written disaster preparedness plan for the emergency care of patients to address fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of its patients. The ASC would coordinate the plan with State and local agencies and would be responsible for conducting annual drills, written evaluations and implementation of any corrections needed to improve the plan.

Comment: One commenter suggested the disaster preparedness plan should only require ASCs to have a plan to provide for the emergency care of the ASC's patients on the premises during events that threaten their health and safety.

Response: We disagree with the commenter. Our intent is for the ASC to have a disaster preparedness plan in place to care not only for the facility's patients on the premises, but also staff, and others who may be in the facility during an emergency if intervention is needed. We believe that the safety of others in the facility is not subject to individual facility decisionmaking. Therefore, we have revised § 416.41(c)(1) accordingly.

Comment: Several commenters were concerned that the proposed language to ''coordinate'' the disaster preparedness plan with State and local agencies could be interpreted by survey officials as a requirement to integrate the ASC facility into State and local disaster relief efforts. The commenters recommended that CMS modify the proposed language and utilize the word ''communicate'' as an alternative.

Response: After consideration of the public comments received, we are retaining the proposed language at § 416.41(c)(2) as final, and are requiring that ASCs coordinate their disaster preparedness plan with State and local authorities. Coordinating the plan with State and local authorities would assist in overall planning efforts and would make known the availability of assets and capabilities that exist during an emergency.

Comment: One commenter expressed support for the requirement that the ASC conduct disaster preparedness drills. However, the commenter believed that to require an ASC to ''immediately implement any corrections'' would be unrealistic.

Response: We agree that an overly literal interpretation of the phrase ''immediately implement any corrections'' located at proposed § 416.41(c)(3) could be problematic. However, we continue to believe an inordinate delay in addressing concerns with the disaster preparedness plan would not be beneficial. In response to the public comment, in this final rule, we have changed § 416.41(c)(3) to read, ''The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.'' We believe this change will provide an appropriate balance between urgency of correction and thoughtful planning.

Comment: One commenter stated that the reference to a ''local'' Medicare-participating or nonparticipating hospital in proposed § 416.41(b)(2) is too vague and suggested an alternate definition.

Response: We understand there have been problems in the past related to the definition of ''local'' when referring to the requirement that ASCs must have an effective procedure for the immediate transfer to a local Medicare-participating hospital or a local nonparticipating hospital. We specifically addressed this issue in the ASC CfCs proposed rule and are reiterating our position here. The definition of local hospital would require the ASC to consider the most appropriate facility to which the ASC would transport its patients in the event of an emergency. If the closest hospital could not accommodate the patient population or the predominant medical emergencies associated with the types of surgeries performed by the ASC, a more distant hospital might also meet the ''local'' definition. In this case, transfer to the more distant hospital would be appropriate. However, under normal circumstances, the ASC would be required to transfer patients to the nearest, most appropriate local hospital, as transfer to a more distant hospital could affect patient health.

After consideration of the public comments received, we are finalizing the proposed revisions to § 416.41 with the following modifications.

In § 416.41(c)(1) of this final rule, we have revised the proposed language to state that the ASC must maintain a written disaster preparedness plan that

provides for the emergency care of patients, staff, and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten ''the health and safety of those in the ASC'' instead of the ''health and safety of its patients'' as proposed.

In § 416.41(c)(3) of this final rule, we have revised the proposed language to state that when the ASC conducts drills, at least annually, to test the disaster preparedness plan's effectiveness, the ASC must complete a written evaluation of each drill and ''promptly'' implement any corrections to the plan, instead of ''immediately'' as proposed. (2) Condition for Coverage: Quality Assessment and Performance Improvement (QAPI) (§ 416.43)

The existing § 416.43, ''Condition for coverage: Evaluation of quality,'' relies on a reactive problem-oriented approach to identify and resolve patient care issues. Failure to meet this requirement has consistently been one of the top 10 deficiencies cited by Medicare surveyors nationwide.

During the last decade, the health care industry has moved beyond the problem-oriented, after-the-fact, corrective approach of quality assurance to an approach that focuses on a proactive, preemptive plan that continuously addresses quality improvement. We proposed that each ASC would develop, implement, and maintain an effective, continuous quality assessment and performance improvement program that stimulates it to constantly monitor and improve its own performance, and to be responsive to the needs, desires, and satisfaction levels of the patients and families it serves. The desired outcome of this proposed requirement would be that an ASC improve its provision of services by proactively implementing its own quality improvement activities. With an effective quality assessment and performance improvement program in place and operating properly, an ASC would be able to prevent the adverse affects of care by identifying the activities that lead to poor patient outcomes. Therefore, an ASC would be free to develop its own individualized program. As proposed, an ASC's QAPI program would not be judged against a specific model.

The proposed QAPI requirement was divided into five standards. Under standard § 416.43(a), ''Program scope,'' an ASC's quality assessment and performance improvement program would include, but not be limited to, an ongoing program that would be able to show measurable improvement in indicators that were associated with improved health outcomes and with the identification and reduction of medical errors. We expect that an ASC would use standards of care and the findings made available in current literature to select indicators to monitor its program. The ASC would measure, analyze, and track these quality indicators, including areas such as adverse patient events, infection control and other aspects of performance that include processes of care and services furnished in the ASC. (''Adverse patient events,'' as used in the field, generally refer to occurrences that are harmful or contrary to the targeted patient outcomes.)

The second proposed standard at § 416.43(b), ''Program data,'' would require the ASC program to incorporate quality indicator data into its QAPI program, including patient care and other relevant data regarding services furnished in the ASC. We did not propose to require that ASCs use any particular process or outcome measures. Proposed standard (b) also would require that data collected by the ASC, regardless of the source of the data elements, would be collected in accordance with the detail and frequency specifications established by the ASC's governing body. Once collected, ASCs would analyze the data to determine the effectiveness and safety of its services, and to identify opportunities for improvement.

The third standard as proposed at § 416.43(c), ''Program activities,'' would require the ASC to set priorities for its performance improvement activities that focused on high risk, high volume and problem-prone areas, that considered the incidence, prevalence and severity of identified problems, and that gave priority to improvement activities that affected health outcomes, patient safety, and quality of care. In § 416.43(c), we also proposed to require the ASC to track adverse patient events, analyze their causes, implement improvements and ensure that the improvements are sustained over time.

The fourth standard as proposed at § 416.43(d), ''Performance improvement projects,'' would require the number and scope of improvement projects that the ASC conducted annually reflect the scope and complexity of the ASC's services and operations. The ASC would document what improvement projects were being conducted, the reasons for conducting them, and the measurable progress achieved on them.

Finally, at § 416.43(e), ''Governing body responsibilities,'' we proposed that the ASC's governing body would be responsible and accountable for ensuring that the ongoing quality improvement program was defined, implemented, and maintained, and that ASC resources were adequately allocated for implementing the facility's program. The governing body would ensure that the program addressed priorities for improved quality of care and patient safety. The governing body would also specify the frequency and detail of the data collection and ensure that all quality improvement actions were evaluated for effectiveness. It would be incumbent on the governing body to lend its full support to all ASC quality assessment and performance improvement efforts.

Comment: Some commenters indicated that the QAPI approach in the 2007 ASC CfCs proposed rule is impractical compared to the existing requirement, ''Evaluation of quality.''

Response: We disagree that the QAPI approach is impractical. The QAPI focus for ASCs, and other Medicare-certified providers and suppliers, is aimed at proactively accessing the quality of care provided and improving health outcomes. A more effective QAPI program will allow ASCs to improve patient care. Many ASCs have already implemented a more effective quality improvement program in place of the current ASC requirement.

Comment: One commenter stated the details of the proposed QAPI program duplicated the requirements imposed by the accrediting bodies.

Response: As stated in the preamble of the 2007 ASC CfCs proposed rule, one of the intents of the revisions to the ASC regulations is to update some of the CfCs. As such, the QAPI CfC is being updated to reflect the current standards of practice in the ASC facility setting. We support the ASC accrediting organizations that have adopted proactive quality improvement programs as current standards of practice. The consistency in philosophy between the Medicare ASC program and those of the accrediting organizations should be comforting to patients and families. Moreover, the specifics of the proposed ASC program are similar to the quality improvement programs that have been included in the Medicare rules governing hospices, and that are being developed for other Medicare facilities. However, we did not intentionally duplicate material from any specific accrediting organization. Because each ASC will determine the specifics of its program, any similarity between it and other QAPI programs, intentional or not, is irrelevant.

Comment: Many commenters expressed enthusiastic support for the updated and expanded QAPI CfC.

Response: We appreciate the overall support for data collection and QAPI. We note that the new regulation does not require ASCs to use electronic health records or any specific software for data collection. ASCs are free to choose the data collection methods and tools that best suit their needs. We do not believe that this new regulation imposes an undue burden on ASCs because it does not require them to obtain sophisticated data collection and analysis computer programs.

Comment: A few commenters expressed concerns as to whether State surveyors would receive adequate training on the new QAPI program, and wondered whether it would be enforced in a consistent manner.

Response: A newly designed surveyor training program is expected to be available online in 2010, thus making uniform training accessible to State surveyors. Once every surveyor is exposed to the same training program, we expect the decisions surveyors make, based on the findings, will be more consistent.

Comment: Several commenters submitted topic areas they would like to include in a QAPI program, such as evaluation and documentation of surgical and anesthesia risk, surgical infection prevention via prophylactic antibiotic administration, utilization of proper medications at admission, and reporting of the number of cases requiring transfer to hospitals due to complications.

Response: ASCs may choose from these and other topic areas when developing their QAPI programs, but not to the exclusion of those topics set out at § 416.43(c).

Comment: One commenter expressed concern that the QAPI CfCs could limit the effectiveness of efforts to ensure safety because, if adopted, the new regulations would allow ASCs to develop and implement their own standards. In addition, the commenter argued, State agencies would have the option to enforce such standards differently among States. Another commenter questioned how CMS would monitor the quality of care being provided across ASCs.

Response: The proposed QAPI standards would serve as an outline to the ASC industry and will aid each ASC in developing, implementing and maintaining its own QAPI program. State survey agencies will be receiving standardized surveyor training to assist in decreasing or eliminating surveyor inconsistency. In addition to training surveyors, we will address any surveyor inconsistency through interpretive guidelines. We note that the QAPI standards do not in any way replace the other substantive standards that ASCs must meet.

We will monitor the quality of care through the results from State survey agencies and deemed national accreditation organizations. The QAPI CfC reflects current industry standards for evaluating quality of care and will help ASCs adopt the universal approach of a proactive program that encourages facilities to make improvements that will prevent patients from being adversely affected. In the near future, we will require ASCs to report quality measures. These quality measures will be utilized to calculate whether ASCs receive full payment updates and as comparative tools for the industry.

Comment: One commenter suggested that CMS include language that would require the ASC governing body to appoint in writing an appropriately trained individual to be responsible for the implementation and oversight of the facility's QAPI program.

Response: While some ASCs may desire to assign a single individual the responsibility of managing the QAPI program, others may find alternate ways that are appropriate to meet this responsibility. ASCs, like other health entities, operate in ways that are advantageous to their own needs. In keeping with this philosophy, we are not requiring that an ASC follow a specific template related to the development and management of its QAPI program. We believe each ASC should have the flexibility to determine how that program should be implemented.

Comment: One commenter suggested that the QAPI program require a leadership component and that the program include activities dealing with high-risk patients, adverse events, and staff resources.

Response: We agree. The QAPI oversight and accountability requirements are part of the Governing body and management CfC; therefore, leadership would be held responsible for direct involvement in the QAPI program. Within the revised QAPI CfC, the ASC QAPI program would be required to set priorities for program activities, focus on high-risk, high-volume, and problem-prone areas, maintain an effective program that includes leadership involvement, and ensure that appropriate resources are allocated for an effective program.

Comment: One commenter expressed concern with the use of the word ''annually'' in proposed § 416.43(d)(1) when referencing ''distinct'' improvement projects and questioned whether this would require a set of separate and distinct projects every year. In addition, the commenter requested that the word ''number'' be removed, to keep the focus on the scope.

Response: We stated in the preamble of the 2007 ASC CfCs proposed rule that we recognize that ASCs serve different populations and provide different services. The words ''distinct,'' ''annually,'' and ''number'' are not new terms for the QAPI Medicare regulations and simply mean that when the ASC conducts its projects, those projects need to take into consideration the types of services it furnishes and any other aspect of its operation so that the effort is meaningful. While we would expect that ASCs will engage in specific projects on an annual basis, there may be a detailed project that will require a long range approach and could be the project that consumes available ASC resources for a period of time, thus making it difficult to undertake more than one project in a particular year.

Comment: One commenter stated that the word ''resources'' in the QAPI CfC should be enhanced by including specific references to staff, time, information systems and training.

Response: We agree that the term ''resources'' should be clarified, and therefore, in this final rule we have revised proposed § 416.43(e)(5) to refer instead to staff, time, information systems and training.

After consideration of the public comments received, and with the exception of § 416.43(e)(5) and some minor nonsubstantive revisions, we are adopting the proposed revisions to § 416.43 as final, without modification. In § 416.43(e)(5), we have modified the proposed requirement to specify that the governing body must allocate adequate ''staff, time, information systems, and training'' to the QAPI program, instead of ''resources,'' as proposed.

(3) Condition for Coverage: Laboratory and Radiologic Services (§ 416.49)

The existing laboratory and radiologic requirement is located at § 416.49. We proposed to divide the condition into a laboratory standard and a radiologic standard. We also proposed to modify the radiology services standard requiring that an ASC meet the Conditions for Coverage for Portable X-Ray Services.

Comment: A few commenters expressed concern that the proposed changes to the radiologic services standard could severely restrict the ability of ASCs to perform procedures requiring imaging guidance. One commenter stated the proposed changes would also impose impractical physician ordering criteria and other

requirements that are not applicable in the ASC setting. In general, while understanding CMS' rationale for presenting the proposed change, commenters believed that this change would disrupt ASC operations on a continuing scale.

Response: The proposed change to the radiologic services requirement was intended to parallel the requirement in the current laboratory standard. That is, an ASC would be required to obtain both laboratory and radiology services from entities that were already certified in accordance with Medicare requirements. We believed this change would establish a higher level of patient safety. We proposed to replace the current requirement that requires ASCs to meet the hospital radiology department requirement (Condition of Participation for Hospitals at § 482.26—Radiologic Services) with the requirement for ASCs to meet the Conditions for Coverage for Portable X-Ray Suppliers (Conditions for Coverage of Portable X-Ray Services at §§ 486.100 through 486.110). These requirements are detailed, thorough, and provide a good foundation for the protection of Medicare beneficiaries. However, it has been pointed out by many of the commenters that the proposed requirements are better suited and more practical for ASCs that perform diagnostic as opposed to imaging services, and that the training requirement for technicians was problematic. The portable x-ray conditions are geared toward the technicians that perform the technical component of diagnostic radiology services without the physician being present, in contrast to ASCs, where the imaging guidance is provided under the direct, personal supervision of the surgeon performing the procedure.

After consideration of the public comments and the impact of the proposed change on an ASC's daily operation, we believe that the change we proposed may be overly restrictive. Therefore, we are not adopting the requirement in proposed § 416.49(b)(2). Instead, we are retaining the existing radiology services requirement applicable to ASCs, at § 482.26 (Hospital Conditions of Participation—Radiologic services). These conditions include the requirements for the safety of patients and personnel, maintenance of equipment, and qualifications for personnel as they relate to radiologic services. However, we have maintained in this final rule the proposed formatting change that separates the laboratory and radiology portion of the existing § 416.49 into two standards.

(4) Condition for Coverage: Patient Rights (§ 416.50)

The proposed patient rights CfC was divided into four standards. Under the first standard, § 416.50(a), ''Notice of rights,'' the ASC would be required to provide the patient or the patient's representative with notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or patient representative understands. We proposed the following: An ASC would have to post the written notice of patient rights in a place or places within the ASC where patients or their representatives are likely to notice it; and the notice of rights would have to include (1) the name, address, and telephone number for a representative in the State agency to whom patients could report complaints about an ASC; and (2) the Web site for the Medicare Beneficiary Ombudsman. We also proposed that the ASC would be responsible for the following: Providing the patient (or his or her representative) with verbal and written information concerning its policies on advance directives; establishing procedures for documenting the existence, submission, investigation and disposition of a patient's written or verbal grievance to the ASC; fully documenting all alleged violations/grievances; and specifying timeframes for the grievance process regarding review of the grievance and provision of a response.

The second proposed standard at § 416.50(b), ''Exercise of rights and respect for property and person,'' specifies the patient's right to exercise his or her rights without being subject to discrimination or reprisal. It also specifies the patient's right to voice grievances regarding treatment or care that is (or fails to be) furnished by the ASC; the patient's right to be fully informed about a treatment or procedure and about the expected outcome; the patient's right, if adjudged incompetent under State law by a court of proper jurisdiction, to have his or her rights exercised by the person appointed under State law to act on the patient's behalf; and the patient's right, if a State court has not adjudged a patient incompetent, to any legal representative designated by the patient in accordance with State law to exercise the patient's rights to the extent allowed by State law.

The third proposed standard at § 416.50(c), ''Privacy and safety,'' would require the ASC to acknowledge the patient has the right to personal privacy, the right to receive care in a safe setting, and the right to be free from all forms of abuse or harassment.

The fourth proposed standard at § 416.50(d), ''Confidentiality of clinical records,'' would require the ASC to acknowledge the patient's right expect that his or her clinical records maintained by the ASC will be held in strict confidentiality. We also proposed that access to or release of patient information and clinical records is permitted only with written consent of the patient or the patient's representative or as authorized by law.

Comment: Some commenters believed CMS should allow more flexibility for ASCs to develop their own process for apprising patients of their rights. Several of the commenters referred CMS to the Title VI, Prohibition Against National Origin Discrimination—Persons with Limited-English Proficiency (42 U.S.C. 2000d *et seq.*). One commenter referred CMS to the Hospital conditions of participation. Both laws permit facility flexibility in informing the patient, or when appropriate, the patient's representative, about the patient's rights. These commenters pointed out that Title VI specifies that the extent of the facility's obligation to provide written translation of documents should be determined by the recipient on a case-by-case basis. They also believed that ASCs' flexible options could include such methods as posting signs and providing information in patient brochures.

Response: We agree that facilities should have flexibility in informing patients of their rights. We also believe that when a patient undergoes a surgical procedure at an ASC that has some physical risk, even a slight risk, the patient needs to be able to have information at hand that explains the procedure(s) at least in a general way. Therefore, we are retaining the proposed requirement that the ASC must post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representatives, if applicable) waiting for treatment. We also are retaining the proposed requirement that the patient be informed verbally and in writing. The written portion may be a printed information sheet or other more sophisticated documents. The document needs to include basic information as required by § 416.50. It may not be practical for an ASC to have available a printed patient rights information document in the language that every patient can understand. However, it is expected that where, a written document is not practical the ASC would make certain that its verbal explanation is clear and thorough. HHS

has published guidance on serving individuals with limited English proficiency in the **Federal Register** at 67 FR 4968 (February 1, 2002).

Comment: Several commenters believed that the Patient rights condition for coverage is too prescriptive and could create administrative burdens which would negatively affect the delivery of care. These commenters suggested CMS delete the phrase ''post the written notice.'' They also recommended that CMS adopt a broader interpretation of the phrase ''informing the patient or patient representative.''

Response: Patient rights and the explanation of patient rights are important elements in this and other Medicare health and safety rules. We agree that procedures that ASCs must follow should be the least prescriptive possible. That is why we have not been explicit in detailing the specifics of the verbal and written information that needs to be included when informing patients of their rights. Regarding the commenters' suggestion to broaden the interpretation of ''informing the patient or patient representative,'' we believe the proposed language is appropriate and we are retaining the language in this final rule.

Comment: Several commenters agreed that disclosure of a physician's ownership interest in a facility is critical, but believe patients should be notified of this financial interest at the point of physician referral and not burden the ASC. The commenters expressed concern that if a beneficiary is not told of a physician's financial interest until a procedure is scheduled, the beneficiary may feel uncomfortable requesting an alternative physician or alternative facility for fear of offending the surgeon. They also asserted that seeking an alternative physician or facility could delay the procedure.

Response: While it may be advantageous to patients to know as early as possible if their physician has an ownership interest in the ASC, we are unable to require physicians to impart that information because we do not regulate physician offices.

Comment: Several commenters suggested that the requirement to propose written ownership disclosure information to patients prior to the first visit embodies the potential to needlessly disrupt patient care, and inconvenience patients. Commenters recommended that CMS adopt the requirement that ownership information be made available to patients upon request or that it be posted in the facility.

Response: Our proposal to require ASCs to be responsible for physician disclosure of financial interests in or ownership of an ASC is based on our existing rules set out at 42 CFR Part 420—Program Integrity. Our goal is to assist Medicare beneficiaries in their efforts to make informed health care decisions through disclosure of all pertinent treatment information, and to achieve a basic level of knowledge across provider settings.

We did not propose to specify in the 2007 ASC CfCs proposed rule how the ownership disclosure information would be provided to the patient, only that it would be provided in writing prior to the first visit to the ASC. To respond to commenters' concerns, we have revised the proposed regulation text to require that the ASC must notify the patient in advance of the date of the procedure regarding physician ownership (for example, it could be at the same time that the ASC provides the package of information regarding pre-surgical testing for the planned ASC surgical procedure). Patients scheduled for a surgical procedure at an ASC almost always receive a package of information containing pre-surgical testing and physical examination requirements to which patients need to adhere. We believe that a simple ''check box'' form could be included in this information packet, for example, specifying whether the referring physician has a financial interest in the facility.

Comment: Several commenters suggested that ASCs should not be required to comply with an advance directive requirement because ASCs perform elective surgeries and because ASC staff are dedicated to doing everything within their power and training to ensure a patient survives the procedure. These commenters further stated that because Medicare does not pay for surgical procedures in the ASC that pose a significant risk to beneficiaries, it is not necessary to require an advance directives policy for ASCs.

The commenters also expressed concern that a patient arriving only 90 minutes in advance of an ASC procedure would not have sufficient time within which to complete an advance directive in addition to the other forms that he or she may be required to complete. Instead, the commenters suggested that advance directives could be made available by the ASC for the patients to obtain and read at their leisure prior to the procedure. The commenters further stated that the proposed requirements would be financially burdensome.

Response: Virtually all Medicare providers and suppliers have an advance directive requirement, with the exception of ASCs and rural health clinics. We agree that explaining an advance directive to patients prior to surgery could be cumbersome depending upon the patient's level of understanding and other circumstances. However, we also believe that patient health and safety must be the primary consideration in determining whether to have ASCs assume some responsibility for an advance directive requirement. We considered the policies behind the Consumer Bill of Rights and Responsibilities (CBRR), which recommended measures to promote and assure health care quality and value and to protect consumers and workers in the health care system. We were interested in whether ASC patients should be treated differently than other patients by virtue of the fact that the surgical procedures they undergo are voluntary and are provided exclusively on an ambulatory basis. CBRR is very specific in stating that consumers must be able to discuss advance directives with their health care provider. We concur. Although surgical procedures performed at ASCs are elective, in the event that any unforeseen complications arise that require transferring the patient to a hospital, an advance directive could be important upon the patient's arrival at the hospital. To ensure consumers' rights and ability to participate in treatment decisions, we believe that ASC health care personnel should discuss the use of advance directives with patients and their designated family members. Discussing advance directives with patients, regardless of the health care setting, is becoming the standard of practice. To actively participate in decisionmaking about their care, consumers must have complete information about their treatment options, including the alternative of no intervention, as well as the risks, benefits, and consequences of any options. Conversely, a health care provider may indicate that it is against its policy to comply with certain advance directives. When such conscience objections are expected to occur, patients should be made aware of it in advance of the date of the procedure. As is the case with patient rights information, advance directive forms can be mailed in the same packet to patients.

Comment: Several commenters were critical of the proposed requirement that ASCs report substantiated and unsubstantiated complaints to State and local authorities. The commenters

argued that unsubstantiated complaints should not be reported, as this might cause inappropriate disclosure of confidential information. Commenters recommended revising this provision to require that all allegations of neglect be promptly reported to a person in authority at the ASC. The commenters indicated that if the ASC determined that the grievance constituted a violation of applicable laws, regulations, or health care program requirements, the ASC would then report the allegation(s) to appropriate State and/or local authorities.

Response: We agree with the commenters. In this final rule, we have revised the proposed ''Submission and investigation of grievances'' requirement at § 416.50(a)(3)(iv) to specify that only substantiated allegations must be reported to State and/or local authorities.

Comment: Commenters believed that confidentiality of clinical records creates unnecessary confusion with the more comprehensive HIPAA privacy standards applicable to ASCs. They believed that permitting access to or release of patient records only with the patient's written consent is more stringent than the HIPAA standards, which permit routine disclosures without patient consent for purposes of payment, treatment, and health care operations. These commenters recommended instead that CMS develop a new standard which cross-references the HIPAA standard for confidentiality of clinical records.

Response: We agree with these commenters and in this final rule have revised the proposed regulation at § 416.50(d) to reflect a cross-reference to the HIPAA standards at 45 CFR Parts 160 and 164.

After consideration of the public comments received, we are finalizing the proposed revisions to § 416.50 with modifications to the following provisions.

In § 416.50(a)(1), we have made editorial revisions, using the phrase ''in advance of the date of the procedure'' instead of the proposed phrase ''prior to furnishing care to the patient and''.

We have made two editorial revisions to § 416.50(a)(1)(i): First, to refer to the ''The ASC's'' notice of rights; and second, to refer to the correct name of the Office of the Medicare Beneficiary Ombudsman.

In § 416.50(a)(1)(ii), we have made a minor editorial revision to the proposed first sentence, using the phrase ''where applicable,'' instead of the proposed phrase ''if applicable''.

In §§ 416.50(a)(2)(i) and (b)(2), we have changed references to ''applicable State law'' to specify ''applicable State health and safety laws''.

In § 416.50(a)(3)(iv), we added the words ''Only substantiated'' to specify the types of allegations that must be reported to ''State or local authorities, or both''.

In § 416.50(d), we have revised the paragraph to reflect a cross-reference to the HIPAA standards at 45 CFR Parts 160 and 164.

(5) Condition for Coverage: Infection Control. (§ 416.51)

The proposed infection control CfC was divided into two standards. Under standard § 416.51(a), ''Sanitary environment,'' we would require the ASC to provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice. We proposed to allow the ASCs to have flexibility in designing their own infection control program that would meet CMS regulations and also meet the needs of their particular facility. The second proposed standard at § 416.51(b), ''Infection control,'' would require the ASC to maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. The program would be required to designate a qualified professional who has training in infection control, integrate the infection control program into the ASC's QAPI program and be responsible for providing a plan of action for preventing, identifying and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement. Because the prevention and control of infection is so critically important to overall patient and staff health and safety, we have proposed to elevate the current standard-level requirement to a condition-level requirement and expand the requirements to include the designation of a qualified professional to direct the infection control program.

Comment: One commenter recommended that CMS include language that requires the ASC to base its policies for its infection control program on nationally recognized guidelines and standards. Another commenter also suggested the use of nationally recognized guidelines as the basis for ASC selection of approved and scientifically based methods and equipment for cleaning, disinfection and sterilization as outlined in nationally recognized guidelines.

Response: In this final rule, we have revised proposed § 416.51(b) to add a provision to read, ''In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.'' As stated in the preamble to the 2007 ASC CFCs proposed rule (72 FR 50477), we expect ASCs to utilize nationally recognized and approved standards and guidelines for their infection control procedures. We stated that we did not want to restrict an ASC's flexibility in utilizing the guidelines that best suited its method of operation and, therefore, have chosen not to accept the comment that we select specific infection control methods as requirements.

Comment: A few commenters asked for clarification regarding the requirement that the designated professional have training in infection control. One commenter suggested the inclusion of examples of nationally recognized organizations that ASCs may seek out for guidance and continuing education. Other commenters suggested the designated infection control individual be identified as an infection control professional rather than infection control officer.

Response: We are not mandating one specific set of guidelines or infection and control standards that an ASC must employ but rather, it must consider, select and implement from nationally recognized guidelines. The preeminent organization that addresses infection issues is the Centers for Disease Control and Prevention. Hospitals and hospital organizations as well as national health care organizations also would have information regarding infection control. Training in infection control is available through a variety of services such as health care organizations, professional associations, and government entities. For example, an ASC could obtain information from the Healthcare Infection Control Practice Advisory Committee (HICPAC), Occupational Safety and Health Administration (OSHA), Association for Professionals in Infection Control and Epidemiology (APIC), Society for Healthcare Epidemiology of America (SHEA), Association of PeriOperative Registered Nurses (AORN) and/or the Association for the Advancement of Medical Instrumentation (AAMI). At this time, we will continue to allow the ASCs the flexibility in setting up the infection control program in a manner which best meets the organization's needs. Moreover, we expect that the ASC will be able to provide verification of staff training and current competency related to infection control standards of practice.

We do not find that it is necessary to associate a title with the qualified professional who directs the program.

Comment: Several commenters requested flexibility in designating an infection control professional to serve multiple facilities that are under common ownership.

Response: There may be rationale for those ASC facilities that are under common ownership to utilize a single infection control professional to direct more than one facility program concurrently. However, we believe that this type of arrangement would potentially hinge on the proximity of the ASCs to each other, the frequency of onsite visits by the designated individual, and the ability of each facility to respond to an infection control issue in a timely manner. We will address these and other issues in more detail in subregulatory guidance.

Comment: One commenter questioned the rationale for elevating infection control to the condition level. A commenter noted that requiring the program to be under the direction of a designated professional who has training in infection control, should not be necessary in the smaller ASC setting.

Response: The infection control requirement located at § 416.44(a)(3) currently requires both large and small ASC organizations to establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities. Considering the huge growth in the ASC industry since we issued the current ASC regulations in 1982, we believe that infection control in a surgical facility should be a high priority. All ASCs, regardless of size, must therefore have an infection control program where the person in charge is knowledgeable and is aware of current advances in the field.

After consideration of the public comments received, we are finalizing the proposed revisions to § 416.51, with some modification.

In the introductory test of § 416.51, we have revised an editorial change to the proposed language, using the phrase ''The ASC,'' instead of the proposed phrase ''The Ambulatory Surgical Center (ASC).'' We are not adopting the proposed ending phrase ''for patients and ASC staff''. Thus, the final language of the introductory text reads: ''The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.''

In § 416.51(b), we have added a sentence to the proposed requirements for infection control which states, ''In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.''

(6) Condition for Coverage—Patient Admission, Assessment, and Discharge (§ 416.52)

The proposed admission, assessment and discharge requirement identified the three general areas that would be applicable to a surgical procedure and the timeframes for completing the assessments to help ASCs ensure they are identifying patient issues and needs in a timely and safe manner.

The proposed patient admission, assessment and discharge condition was divided into three standards. The first standard, § 416.52(a), ''Admission and pre-surgical assessment,'' would require the patient to have a comprehensive medical history and physical assessment completed by a physician or other qualified practitioner in accordance with State law and ASC policy not more than 30 days before the date of the scheduled surgery. The purpose of this medical history and physical assessment not more than 30 days before the date of the scheduled surgery is to ensure the medical professionals at the ASC have up-to-date and pertinent patient information available to perform safe and effective surgical procedures. In the second standard, § 416.52(b), ''Post-surgical assessment,'' we proposed that a thorough assessment of the patient's post-surgical condition must be completed and documented, and that any post-surgical needs are addressed and included in the discharge notes. In the third standard, § 416.52(c), ''Discharge,'' we proposed that the ASC must provide each patient with written discharge instructions; ensure the patient has a safe transition to home; ensure post-surgical needs are met; ensure each patient has a discharge order; and ensure the discharge order indicates the patient has been evaluated for proper anesthesia and medical recovery.

Comment: The majority of commenters supported the overall goals of the proposed patient admission, assessment, and discharge requirement. Several commenters suggested the removal of the specific language, ''who performed the surgery or procedures unless otherwise specified by State law'' found in proposed § 416.52(c)(3). Several other commenters questioned the rationale for the addition of the condition itself and believed the requirement is more stringent than that developed by accrediting bodies.

Response: After consideration of the public comments received and further review of the existing standards for assessment, anesthesia evaluation, and discharge, we have modified some of our proposed requirements in this final rule. We are not adopting that portion of proposed § 416.52(a)(2) that would require the pre-surgical assessment to include a determination of the patient's mental ability to undergo surgery. This may be beyond the scope of a surgical team.

Comment: Several commenters argued that CMS should not require ASCs to assess a patient's subjective ''mental ability'' to undergo surgery, especially where such an assessment conflicts with the legal right of a patient to make his or her own health care decisions or to have those decisions made by his or her designated representatives rather than by health care providers. One commenter had two suggestions. The first was that CMS change the language at proposed § 416.52(a)(1) to include the requirement that the physician who will be performing the procedure complete the comprehensive history and physical assessment, and that if the physician delegates this responsibility to another physician, such as the primary care physician, the operating physician review and authenticate the assessment prior to the date of surgery. Secondly, the commenter requested that CMS change the language at proposed § 416.52(a)(3) to state that ''the patient's medical history and physical assessment must be placed in the patient's medical record prior to the patient being taken to the operating room,'' rather than ''before the surgical procedure is started.''

Response: It is customary for the patient's primary care physician to perform the patient's comprehensive history and physical assessment, and it is also customary for the operating physician to determine from the pre-surgical assessment that is based on the required history and physical assessment requirement at § 416.52(a)(2) of the final rule that the patient will be able to tolerate surgery. We believe the second suggestion of the commenter for changes to § 416.52(a)(3) is a reiteration of what was proposed. However, in the final rule we have changed the language from ''before the surgical procedure is started'' to ''prior to the surgical procedure.''

Comment: Some commenters suggested alternative language to the post-surgical assessment located at § 416.52(b)(1). Commenters stated that a thorough assessment would require a review of all body systems and that it is not standard practice to do full body

assessments post-operatively and there is no evidence-based clinical rationale for such a broad requirement. One commenter suggested that well-trained professional nurses are capable of performing patient monitoring and assessment for anesthesia recovery.

Response: We agree and in this final rule have revised the requirement to allow for sufficient flexibility based on ASC policy to determine the assessment appropriate to the nature and scope of the procedure performed as well as the specific medical condition of the individual patient. The final regulation text at § 416.52(b)(1) reads, ''The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience, in accordance with applicable State health and safety laws, standards of practice, and ASC policy.''

Comment: Some commenters indicated the requirement in the proposed Discharge standard at § 416.52(c)(2) that the ASC ensure that the patient have a safe transition to home was overly broad and opposed the language. Commenters were concerned that the language could be interpreted to mean the ASCs would be obligated to assume full responsibility for transporting patients to their homes using ambulances or other extraordinary precautions. They stated that there was no way for ASCs to ''ensure'' against car accidents or other events outside of their control that could interfere with a patient's safe transition to home.

Response: We agree that the proposed language could be construed too broadly and that there would be room for interpretation about the ASC's responsibility for patients after they had left the facility enroute to their home. Therefore, in this final rule we have removed that proposed requirement to limit ASC responsibility.

Comment: Many commenters suggested CMS move the discharge language located in the existing Surgical services requirement at § 416.42(c) to the new Patient admission, assessment, and discharge requirement at proposed § 416.52. Commenters also recommended that CMS expand the requirement currently set out at § 416.42(a) to specify that other qualified anesthesia providers, in addition to a physician, may evaluate each patient's proper anesthesia recovery before discharge from the ASC. In addition, commenters suggested that CMS group all the discharge requirements together in one section.

Response: As noted previously, we have clarified and amended the language at proposed § 416.52(b)(1) in this final rule to state that the patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience, in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

In addition, it is customary for the operating physician to write a discharge order indicating ''the patient may be discharged when stable.'' Thus, in this final rule we are retaining, with some modification, the proposed language at § 416.52(c)(2) which now states: ''Ensure each patient has a discharge order signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.'' These modifications to our proposal do not detract from the intent or value of the requirement.

Based on the public comments we received regarding proposed § 416.52(b)(1) and our corresponding changes, we believe a companion change can be made to § 416.42. We believe that discharged patients should be free of the effects of anesthesia to the greatest extent possible. Because we are permitting a physician, other qualified practitioner, or a registered nurse with experience in post-operative care at a minimum in § 416.52(b)(1) to assess and document the patient's post-surgical condition, we believe that we should permit a qualified practitioner, as defined at § 410.69(b), to determine if the lingering effects of anesthesia adversely affect discharge as noted in proposed § 416.42(a)(2). Therefore, in this final rule, we are conforming the existing regulation at § 416.42(a) (we refer readers to Subpart C—Specific Conditions for coverage—Surgical services) to the policy proposed at § 416.52(c) of the proposed rule by separating the existing two sentences into § 416.42(a)(1) and § 416.42(a)(2), and we are expanding the language under paragraph (a)(2) to state that ''before discharge from the ASC, each patient must be evaluated by a physician or by a practitioner qualified to administer anesthesia as defined at § 410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery.'' These changes will provide flexibility for an ASC and are reflective of current practice.

We agree with the suggestion that we group the discharge requirements together in one section and have moved the requirement located at existing § 416.42(c), ''Standard: Discharge,'' to the new patient admission, assessment and discharge requirement at § 416.52 (c)(3). As adopted, this paragraph requires the ASC to ''Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.''

After consideration of the public comments received, we are adopting the provisions of proposed § 416.52 as final with modifications as discussed below. As discussed earlier, we also are adopting revisions to §§ 416.42(a) and 416.42(c) based on public comments received regarding proposed changes to § 416.52(c) to conform them to the final policy.

In § 416.52, we revised the proposed introductory language to state that, ''The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.''

In § 416.52(a)(1), we have changed the proposed language ''State law and ASC policy'' to specify ''applicable State health and safety laws, standards of practice, and ASC policy''.

In § 416.52(a)(2), we added language to state that the pre-surgical assessment must be completed by a physician ''or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy'' and that the documented medical history and physical assessment includes ''documentation of any allergies to drugs and biologicals''. We are not adopting the proposed language that would have required that ''The assessment must include documentation to determine the patient's mental ability to undergo the surgical procedure.''

In § 416.52(a)(3), we have changed the language ''before the surgical procedure is started'' to ''prior to the surgical procedure''.

In § 416.52(b)(1), we have revised the proposed language to state ''The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with post-operative care experience at a minimum, in accordance with applicable State health and safety laws, standards of practice, and ASC policy.''

In § 416.52(c)(1), we have added language to state that the ASC must, ''Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a followup appointment with the

physician, and ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for followup care.''

In § 416.52(c)(2), we did not adopt the proposed requirement that the ASC must ensure ''the patient has a safe transition to home and that the post-surgical needs are met.''

In § 416.52(c)(3), we have renumbered the proposed section as § 416.52(c)(2) and revised the proposed first sentence to state that the ASC must, ''Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.''

We are not adopting as final the proposed language of § 416.52(c)(3), which would have required that ''The discharge order must indicate that the patient has been evaluated for proper anesthesia and medical recovery.'' We have moved the provision of existing § 416.42(c) to new final § 416.52(c)(3), and made editorial revisions so that the provision now reads, ''Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.''

In § 416.42(a), we have separated the two existing sentences into two subsections and added language in the newly designated § 416.42(a)(2) to permit ''a practitioner qualified to administer anesthesia as defined at § 410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy'' or a physician to evaluate a patient for proper anesthesia recovery before the patient is discharged from the ASC.

In § 416.42(c), we have made minor editorial revisions to the existing requirement and moved the requirement to new § 416.52(c)(3).

c. Comments Outside the Scope of the Proposed Rule

Comment: One commenter requested that CMS change emergency equipment language to say ''available in the ASC'' instead of the current language ''available to the operating rooms.'' Other commenters suggested that CMS allow surgeons to have consulting privileges instead of admitting privileges at local hospitals. Some commenters suggested that CMS remove the requirement that mandates all ASCs have a mechanical ventilator, or exclude ASCs not administering general anesthesia from the requirement to have a ventilator in the ASC. Some commenters expressed concern over the variance in State licensing requirements. One commenter recommended that CMS establish an ''ASC compare'' site for comparison of safety and quality of services. Other commenters suggested that CMS add language to allow other individuals permitted by State law or regulation to order drugs or biologicals. Finally, one commenter requested that CMS amend the waiting area requirement.

Response: These issues are outside the scope of the 2007 ASC CfCs proposed rule and are not addressed in this final rule.

C. Updates to the Revised ASC Payment System

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 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, Public Law 103–432, requires us to establish 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), Public Law 108–173, added section 1833(i)(2)(D) to 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 to require 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), Public Law 109–171, amended section 1833(i)(2) of the Act by adding a new subparagraph (E) to place a limitation on payment amounts for surgical procedures in ASCs. 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. This provision applied to 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 109(b) of the Medicare Improvements and Extension Act of 2006 of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA), Public Law 109–432, amended section 1833(i) of the Act, in part, by redesignating clause (iv) as clause (v) and by adding a new clause (iv) to paragraph (2)(D) and adding paragraph (7)(A), which authorize the Secretary 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 paragraph (7)(B), which requires that certain quality of care reporting requirements mandated for hospitals paid under the OPPS, under section 109(a) of the MIEA–TRHCA, be applied in a similar manner to ASCs unless otherwise specified by the Secretary.

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. 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. In that final rule, we also established a policy for updating on an annual calendar year basis the ASC conversion factor, the relative payment weights and APC assignments, the ASC payment rates, and the list of procedures for which Medicare would not make an ASC payment. 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).

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 practice expense (PE) relative value units (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.

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, 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. Prior to the revised ASC payment system, procedures were excluded from the ASC list of covered surgical procedures based on whether they were expected to require more than four hours of recovery time. Both the previous 4-hour limit on the expected length of recovery time and the current criterion related to the expected need for active medical monitoring at midnight following the procedure were based on our longstanding requirement that procedures on the Medicare ASC list of covered surgical procedures do not require an extended recovery time and do not require an ''overnight'' stay.

We defined 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 provedures 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 revised ASC payment system 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 revised 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 services, for which separate payment is made under the OPPS, 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; and certain radiology services. These covered ancillary services are specified in § 416.164(b) and are eligible for separate ASC payment (72 FR 42495). Payment for ancillary services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

The full CY 2008 lists of ASC covered surgical procedures and covered ancillary services are included in Addenda AA and BB, respectively, to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66945 through 66993 and 67165 through 67188).

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 ASC payment systems (§ 416.173; 72 FR 42535). In addition, 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 codes 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.

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, 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.

Comment: Commenters provided a number of general suggestions related to the ASC list of covered surgical procedures. They contended that CMS should not restrict which procedures are payable in ASCs any more than CMS restricts which procedures are payable in HOPDs. The commenters also enumerated more specific modifications that they said would make the ASC payment system more equitable. They suggested that CMS allow payment for procedures reported by unlisted codes when the only possible procedures reported by the unlisted code are from anatomic sites that could not possibly pose a potential risk to beneficiary safety. They gave as an example of such

an unlisted code, CPT code 67999 (Unlisted procedure, eyelids). In addition, the commenters recommended that CMS automatically evaluate, for addition to the ASC list of covered surgical procedures, all procedures that are removed from the OPPS inpatient list and that, in all cases, CMS should provide specific reasons that procedures are excluded from the ASC list of covered surgical procedures. The commenters questioned why there are instances in which all but one or two of the procedures in a given APC are included on the ASC list. They stated that the APCs are clinically homogeneous and that as such, all of the procedures in an APC should be determined either to be excluded from or included on the ASC list. Finally, some commenters requested that ASCs be paid for certain services outside the CPT surgical code range, including certain Category III CPT codes and radiology services when packaged surgical procedures would also be performed.

Response: We appreciate the commenters' suggestions regarding the consistency of the decisions about which procedures are excluded from the ASC list. However, as we explained in the August 2, 2007 revised ASC payment system final rule (72 FR 42479), we do not believe that all procedures that are appropriate for performance in HOPDs are appropriate in ASCs. HOPDs are able to provide much higher acuity care than ASCs. ASCs have neither patient safety standards consistent with those in place for hospitals, nor are they required to have the trained staff and equipment needed to provide the breadth and intensity of care that hospitals are required to maintain. Therefore, we will not modify our policy to exclude from the ASC list of covered surgical procedures only those procedures for which no payment is made in HOPDs.

We do not agree with the commenters' recommendation that we include certain unlisted codes on the list of covered procedures. Even though it may be highly unlikely that any procedures that would be expected to pose a risk to beneficiary safety or to require an overnight stay would be reported by an unlisted code from certain anatomic sites, we cannot know what surgical procedure is being reported by an unlisted code, and because we cannot evaluate any such procedure, we believe that we must exclude unlisted codes from the list of covered surgical procedures.

Each year in the annual OPPS/ASC proposed rule, we present the procedures we are proposing to remove from the OPPS inpatient list for the upcoming calendar year. In the past, we have not consistently reviewed procedures removed from the OPPS inpatient list to evaluate their appropriateness for payment under the ASC payment system. Because our policy under the revised ASC payment system is to annually evaluate all surgical procedures that are excluded from the ASC list for potential inclusion in the following year, we believe it is appropriate to include a review of surgical procedures that are proposed for removal from the OPPS inpatient list as part of our annual review of procedures excluded from the ASC list of covered surgical procedures. Therefore, we are adopting the commenters' suggestion to evaluate for appropriateness of ASC payment surgical procedures removed from the OPPS inpatient list. We will include in the annual OPPS/ASC proposed rule, our proposals to include or not include on the ASC list of covered surgical procedures those procedures proposed for removal from the OPPS inpatient list. We will include our final decisions in the OPPS/ASC final rule with comment period.

We do not agree with the commenters' request that we provide specific reasons for our decisions to exclude procedures from the ASC list other than that we believe a procedure is expected to pose a significant risk to beneficiary safety or to require an overnight stay. We believe that these reasons are sufficiently specific. Our decisions to exclude procedures from the ASC list are based on a number of the criteria listed at § 416.166, and we believe that it would be unnecessary and overly burdensome to list each and every reason for those decisions.

For each of the specific examples that the commenters provided of inconsistent ASC treatment of procedures assigned to a single APC under the OPPS, we have evaluated the individual procedures for inclusion on the ASC list and each is discussed in section XV.E.1.a. of this final rule with comment period. During our development of the proposed CY 2010 update to the ASC payment system, we will perform a comprehensive review of the APCs to address other potential inconsistencies.

Finally, currently the revised ASC payment system provides payment only for surgical procedures within the surgical code range of CPT and for those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to surgical procedures that are on the ASC list of covered surgical procedures (72 FR 42478). Furthermore, radiology services are only separately paid when they are provided integral to the performance of covered surgical procedures (72 FR 42498). Therefore, we will not provide ASC payment in CY 2009 for services that do not meet these criteria. However, we note that while section 1832(a)(2)(F) of the Act defines the ASC benefit as ''facility services furnished in connection with surgical procedures specified by the Secretary,'' some stakeholders have raised the possibility of ASCs providing a broader range of services in the future, including services such as cardiac catheterization and hyperbaric oxygen therapy (which are included in the medicine range of CPT codes). While we are not making any changes to the existing criteria for ASC services for CY 2009, we may consider proposing changes in the future.

After consideration of the public comments received, we are accepting the commenters' recommendation to include in our annual evaluation of excluded surgical procedures all procedures proposed for removal from the OPPS inpatient list, and agree to evaluate the OPPS APCs for potential inconsistencies related to exclusion from the ASC list of covered surgical procedures. We are not accepting the commenters' recommendations to not exclude all procedures reported by unlisted codes and procedures that we determine would be expected to pose a significant risk to beneficiary safety or require an overnight stay. Further, we also are not accepting the commenters' recommendation that CMS provide more specific reasons for its decisions regarding exclusion of specific procedures from the ASC list of covered surgical procedures or their recommendation that we pay ASCs for services in CY 2009 that do not meet the current criteria for ASC services.

D. Treatment of New Codes

1. Treatment of New Category I and III CPT Codes and Level II HCPCS Codes

We finalized a policy in the August 2, 2007 final rule to evaluate each year all new Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, 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). In addition, we identify new codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. New HCPCS codes that are released in

the summer through the fall of each year, to be effective January 1, are included in the final rule with comment period updating the ASC payment system for the following calendar year. These new 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 status. The interim payment indicators assigned to the new codes under the revised ASC payment system are subject to public comment in that final rule with comment period. These interim determinations must be made in the OPPS/ASC final rule with comment period because, in general, the new HCPCS codes and their descriptors for the upcoming calendar year are not available at the time of development of the OPPS/ASC proposed rule. We will respond to those comments in the OPPS/ASC final rule with comment period for the following calendar year. We proposed to continue this recognition process for CY 2009 (73 FR 41525).

We did not receive any public comments regarding this proposal. For CY 2009, we are continuing our established policy for recognizing new Category I and Category III CPT codes and Level II HCPCS codes.

In addition, we proposed to continue our policy of implementing through the ASC quarterly update process new mid-year CPT codes, generally Category III CPT codes, that the AMA releases in January to become effective the following July (73 FR 41525). Therefore, we proposed to include in Addenda AA or BB, as appropriate, to the CY 2009 OPPS/ASC final rule with comment period the new Category III CPT codes released in January 2008 for implementation on July 1, 2008 (through the ASC quarterly update process) that we identify as ASC covered services. Similarly, we proposed to include in Addenda AA and BB to this final rule with comment period any new Category III CPT codes that the AMA releases in July 2008 to be effective on January 1, 2009 that we identify as ASC covered services. However, only those new Category III CPT codes implemented effective January 1, 2009 are designated by comment indicator ''NI'' in the Addenda to this CY 2009 OPPS/ASC final rule with comment period, to indicate that we have assigned them an interim payment status which is subject to public comment. The Category III CPT codes implemented in July 2008 for ASC payment, which appeared in Table 36 of the CY 2009 OPPS/ASC proposed rule (73 FR 41525), were subject to comment on the CY 2009 OPPS/ASC proposed rule, and we proposed to finalize their payment indicators in this CY 2009 OPPS/ASC final rule with comment period. We proposed to assign payment indicator ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) to each of the three new codes. Because new Category III CPT codes that become effective for July are not available to CMS 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 are included in the appropriate Addenda to the OPPS/ASC final rule with comment period.

We did not receive any public comments regarding this proposal. We are continuing our established policy for recognizing new mid-year CPT codes, and the new mid-year codes implemented in July 2008 are displayed in Table 40 below, as well as in Addendum AA to this final rule with comment period.

TABLE 40—NEW CATEGORY III CPT CODES IMPLEMENTED IN JULY 2008 FOR ASC PAYMENT

CY 2009 HCPCS code	CY 2009 Long descriptor	Final CY 2009 ASC payment indicator
0190T	Placement of intraocular radiation source applicator	G2
0191T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach.	G2
0192T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach.	G2

2. Treatment of New Level II HCPCS Codes Implemented in April and July 2008

New Level II HCPCS codes may describe covered surgical procedures or covered ancillary services. All new Level II HCPCS codes implemented in April and July 2008 for ASCs describe covered ancillary services. During the second quarter of CY 2008, we added to the list of covered ancillary services a total of four new Level II HCPCS codes for drugs and biologicals because they are eligible for separate payment under the OPPS. Those HCPCS codes are: C9241 (Injection, doripenem, 10 mg); Q4096 (Injection, von willebrand factor complex, human, ristocetin cofactor (not otherwise specified), per i.u. VWF.RCO); Q4097 (Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g., liquid), 500 mg); and Q4098 (Injection, iron dextran, 50 mg). Similarly, for the third quarter of CY 2008, we added a total of four new Level II HCPCS codes to the list of ASC covered ancillary services for drugs and biologicals because they are eligible for separate payment under the OPPS. Those HCPCS codes are: C9242 (Injection, fosaprepitant, 1 mg); C9356 (Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter); C9357 (Dermal substitute, granulated cross-linked collagen and glycosaminoglycan matrix (Flowable Wound Matrix), 1 cc); and C9358 (Dermal substitute, native, non-denatured collagen (SurgiMend Collagen Matrix), per 0.5 square centimeters).

We assigned the payment indicator ''K2'' (Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate) for all of these new Level II HCPCS codes and added them to the list of covered ancillary services either through the April update (Transmittal 1488, Change Request 5994, dated April 9, 2008) or the July update (Transmittal 1540, Change Request 6095, dated June 20, 2008) of the CY 2008 ASC payment system. In the CY 2009 OPPS/ASC proposed rule (73 FR 41526), we solicited public comment on the proposed ASC payment indicators and payment rates for these codes, as listed in Tables 37 and 38 of the proposed rule. The codes listed in

Table 37 also were included in Addendum BB to the CY 2009 OPPS/ASC proposed rule. Those HCPCS codes are paid in ASCs, beginning in either April or July 2008, based on the ASC rates posted for the appropriate calendar quarter on the CMS Web site at: *http://www.cms.hhs.gov/ASCPayment/*.

However, because HCPCS codes that become effective for July are not available to CMS in time for incorporation into the Addenda to the OPPS/ASC proposed rule, our policy is to include the HCPCS codes, their proposed payment indicators, and proposed payments rates in the preamble to the proposed rule but not in the Addenda to the proposed rule. The HCPCS codes and their final payment indicators and rates are included in the appropriate Addenda to the OPPS/ASC final rule with comment period. Thus, the codes implemented by the July 2008 ASC update and their proposed CY 2009 payment rates (based on July 2008 ASP data) that were displayed in Table 38 of the CY 2009 OPPS/ASC proposed rule were not included in Addendum BB to the CY 2009 OPPS/ASC proposed rule. We proposed to include the new HCPCS codes displayed in Tables 37 and 38 and, for the codes in Table 37, in Addendum BB to the list of covered ancillary services and to incorporate all of them into Addendum BB to this CY 2009 OPPS/ASC final rule with comment period, consistent with our annual update policy.

For CY 2009, the CMS HCPCS Workgroup created permanent HCPCS J-codes for the four codes that were implemented in April 2008 and one of the codes that was implemented in July 2008, and we will be recognizing these HCPCS J-codes for payment of these drugs and biologicals under the CY 2009 ASC payment system, consistent with our general policy to use permanent HCPCS codes, if appropriate, for the reporting of drugs. Tables 41 and 42 show the new permanent HCPCS J-codes that replace several HCPCS C-codes and Q-codes that will be deleted, effective December 31, 2008. The HCPCS J-codes, effective January 1, 2009, describe the same drugs and the same dosages as the HCPCS codes they are replacing. Because the new HCPCS codes describe the same drugs and the same dosages as do the current codes, there is no effect on the payment indicators.

In addition, a new HCPCS Q-code, Q4114, that is effective January 1, 2009, was created to replace HCPCS code C9357. Although the long descriptor is changed, the new code describes the same biological and dosage as did HCPCS code C9357. Therefore, we will recognize HCPCS code Q4114 for payment under the CY 2009 ASC payment system, and no change to the payment indicator of the HCPCS code is warranted.

We did not receive any public comments regarding our proposal. We are adopting the ASC payment indicators for the new Level II HCPCS codes implemented in April and July 2008 as shown in Tables 41 and 42, respectively. Moreover, we are adopting as final the replacement HCPCS codes, specifically J1267, J7186, J1459, J1750, and J1453, as well as HCPCS codes C9356, Q4114, and C9358, as show in Tables 41 and 42 below, and in Addendum BB to this final rule with comment period.

TABLE 41—LEVEL II HCPCS CODES IMPLEMENTED IN APRIL 2008

CY 2008 HCPCS code	CY 2009 HCPCS code	CY 2009 Long descriptor	Final CY 2009 ASC payment indicator
C9241	J1267	Injection, doripenem, 10 mg	K2
Q4096	J7186	Injection, antihemophilic factor viii/von willebrand factor complex (human), per factor viii i.u.	K2
Q4097	J1459	Injection, immune globulin (Privigen), intravenous, non-lyophilized (e.g. liquid), 500 mg.	K2
Q4098	J1750	Injection, iron dextran, 50 mg	K2

TABLE 42—LEVEL II HCPCS CODES IMPLEMENTED IN JULY 2008

CY 2008 HCPCS code	CY 2009 HCPCS code	CY 2009 Long descriptor	Final CY 2009 ASC payment indicator
C9242	J1453	Injection, fosaprepitant, 1 mg	K2
C9356	C9356	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per square centimeter.	K2
C9357	Q4114	Allograft, Integra Flowable Wound Matrix, injectible, 1 cc	K2
C9358	C9358	Dermal substitute, native, non-denatured collagen (SurgiMend Collagen Matrix), per 0.5 square centimeters.	K2

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

1. Covered Surgical Procedures

a. Additions to the List of ASC Covered Surgical Procedures

In the CY 2009 OPPS/ASC proposed rule (73 FR 41526), we proposed to update the ASC list of covered surgical procedures by adding nine procedures to the list. Three of the nine procedures, specifically CPT code 0190T (Placement of intraocular radiation source applicator), CPT code 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; internal approach), and CPT code 0192T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach) are new Category III CPT codes that became effective July 1, 2008 and were implemented in the July 2008 ASC update. The other six procedures were among those excluded from the ASC list for CY 2008 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. During our annual review of excluded codes in which we used the most recent

available utilization data, we identified the following six procedures that we believed should no longer be excluded from the ASC list: CPT code 31293 (Nasal/sinus endoscopy, surgical; with medial orbital wall and inferior orbital wall decompression); CPT code 34490 (Thrombectomy, direct or with catheter; axillary and subclavian vein, by arm incision); CPT code 36455 (Exchange transfusion, blood; other than newborn); CPT code 49324 (Laparoscopy, surgical; with drainage of lymphocele to peritoneal cavity); CPT code 49325 (Laparoscopy, surgical; with revision of previously placed intraperitoneal cannula or catheter, with removal of intraluminal obstructive material if performed); and CPT code 49326 (Laparoscopy, surgical; with omentopexy (omental tacking procedure)). The nine codes that we proposed to add to the ASC list of covered surgical procedures and their proposed CY 2009 payment indicator ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) were displayed in Table 39 of the CY 2009 OPPS/ASC proposed rule (73 FR 41527).

Comment: Commenters requested that CMS add a number of additional procedures to the ASC list of covered surgical procedures. Some commenters requested that CMS add CPT codes 15170 (Acellular dermal replacement, trunk, arms, legs; first 100 sq cm or less, or 1% of body area of infants and children); 15171 (Acellular dermal replacement, trunk, arms, legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof); 15175 (Acellular dermal replacement, 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 15176 (Acellular dermal replacement, 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) because they believed that those procedures met the criteria CMS has established for ASC payment and are comparable to surgical procedures already included on the list of covered surgical procedures.

Response: We reviewed these codes and agree with the commenters that the procedures would not be expected to pose a significant risk to beneficiary safety and to require an overnight stay. Therefore, we are adding these procedures to the ASC list of covered surgical procedures, and we have assigned payment indicator ''G2'' to CPT codes 15170, 15171, 15175 and 15176 in Addendum AA to this final rule with comment period.

Comment: Several commenters requested that CMS add to the ASC list the procedures reported by CPT codes 21385 (Open treatment of orbital floor blowout fracture; transantral approach (Caldwell-Luc type operation); 21386 (Open treatment of orbital floor blowout fracture; periorbital approach); and 21387 (Open treatment of orbital floor blowout fracture; combined approach). The commenters stated that although the majority of these cases result from trauma and, therefore, present in the hospital emergency department, delayed presentation occasionally occurs. In those cases, they argued that the ASC setting would be an appropriate site for the procedures because blood loss is minimal and patients do not require an overnight stay. They also noted that CMS had proposed to remove CPT codes 21386 and 21387 from the OPPS inpatient list for CY 2009 and that because these procedures would be payable in the hospital outpatient setting, they requested that CMS provide a reason for its decision to continue to exclude the procedures from the ASC list.

Response: Although we agree with the commenters that these procedures rarely would be performed in ASCs because of the typically urgent nature of their presentation, our medical advisors found that the typical post-operative course for the procedures includes a need for active medical monitoring for at least 24 hours following surgery. Based on our review of the three procedures, we will continue to exclude them from the list of covered surgical procedures for CY 2009 because we expect that they would pose a significant risk to beneficiary safety or require an overnight stay following surgery, even on those rare occasions that the beneficiary presents in the ASC after a delay in seeking treatment.

Comment: Commenters requested the addition of CPT codes 29867 (Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)) and 29868 (Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral) to the ASC list of covered surgical procedures because they would not be expected to require overnight care and are comparable to procedures such as CPT code 29880 (Arthroscopy, knee, surgical; with meniscectomy (medial AND lateral, including any meniscal shaving)) that are included on the ASC list.

Response: We reviewed the utilization and clinical information for the two procedures discussed. We continue to believe that the post-operative care that is likely to be required for the procedures includes inpatient hospital care in many cases, and we expect would at least require active medical monitoring and care at midnight following the procedure. Therefore, we will continue to exclude CPT codes 29867 and 29868 from the ASC list of covered surgical procedures for CY 2009.

Comment: Commenters requested that CMS add CPT codes 31292 (Nasal/sinus endoscopy, surgical; with medial or inferior orbital wall decompression) and 31294 (Nasal/sinus endoscopy, surgical; with optic nerve decompression) to the ASC list. Commenters contended that because CMS proposed to add CPT code 31293 (Nasal/sinus endoscopy, surgical; with medial orbital wall and inferior wall decompression) to the list for CY 2009, CMS should also add these two closely related procedures. The three procedures were proposed for assignment to APC 0075 (Level V Endoscopy Upper Airway) under the OPPS, and the commenters indicated that CPT codes 31292 and 31294 were the only procedures assigned to that APC that are not on the ASC list. They stated their belief that the clinical homogeneity of the APC provides supporting evidence that these two procedures should also be included for payment in ASCs.

Response: In response to the public comments, we reexamined CPT codes 31292 and 31294 and continue to expect that these procedures would pose a significant safety risk to beneficiaries in ASCs or require monitoring at midnight following the surgery. In addition, in reviewing those procedures, we reevaluated our proposed addition of CPT code 31293 to the ASC list and determined that it should remain excluded from the ASC list. Our medical advisors agreed with the commenters that the procedure reported by CPT code 31293 is closely related to those procedures reported using CPT codes 31292 and 31294 and determined that it, too, would be expected to pose a significant risk to beneficiary safety and require an overnight stay. Therefore, we will not add CPT codes 31292 and 31294 to the ASC list, and we also are not finalizing our proposal to add CPT code 31293 to the ASC list of covered surgical procedures for CY 2009.

Comment: One commenter requested that CMS add CPT code 37205 (Transcatheter placement of an intravascular stent(s) (except coronary,

carotid, and vertebral vessel), percutaneous; initial vessel) to the ASC list of covered surgical procedures for CY 2009. The commenter said that one of the procedures described by CPT code 37205 is increasingly employed by surgeons in attempts to extend the patency of a fistula or graft for hemodialysis longer than may be accomplished by angioplasty alone. The commenter believed that continued exclusion of CPT code 37205 from the ASC list would interfere with the physician-patient decision-making process related to the most appropriate site for the service to be provided. Further, the commenter noted that CPT code 37205 is used to report other surgeries, some of which may not be appropriately provided in ASCs, and strongly encouraged CMS to consider creating a separate code(s) for the placement of dialysis vascular access stents, similar to the hemodialysis access angioplasty HCPCS G-codes (G0392 (Transluminal balloon angioplasty, percutaneous; for maintenance of hemodialysis access, arteriovenous fistula or graft; arterial) and G0393 (Transluminal balloon angioplasty, percutaneous; for maintenance of hemodialysis access, arteriovenous fistula or graft; venous)) created for CY 2007.

Response: We continue to find that many of the procedures that could be reported by CPT code 37205 would be expected to present significant risks to beneficiary safety if they were to be performed in ASCs. Therefore, we will continue to exclude this procedure from the ASC list for CY 2009. However, we understand the commenter's points that the procedure, when performed peripherally, may be valuable for maintaining vascular access for dialysis patients and that the clinical characteristics of stenting to maintain hemodialysis access may differ from the features of other surgical procedures that could also be described by CPT code 37205. As we develop the proposals to update the OPPS and ASC payment system for CY 2010, we will consider the commenter's recommendation regarding the creation of a HCPCS G-code to describe the insertion of vascular stents for the purpose of extending the patency of fistulae or grafts for dialysis patients.

Comment: One commenter requested that CMS add CPT code 50593 (Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy) to the ASC list of covered surgical procedures. The commenter noted that the procedure is assigned to APC 0423 (Level II Percutaneous Abdominal and Biliary Procedures) under the OPPS and is the only procedure in that APC that is excluded from the ASC list. The commenter believed that, because APCs are clinically homogeneous, CPT code 50593 should also be included for ASC payment.

Response: Our medical advisors reviewed the procedure described by CPT code 50593. We have no physician claims data to indicate in which sites-of-service the procedure was performed because the Category I CPT code was new for CY 2008, and physician data are not available for the predecessor Category III CPT code. Based on the judgment of our medical advisors, we continue to expect that the procedure would pose a significant safety risk to beneficiaries if performed in an ASC. When we prepare the CY 2010 OPPS/ASC proposed rule, we will review utilization data that have become available for the procedure.

Comment: Commenters on the CY 2008 OPPS/ASC final rule with comment period and commenters on the CY 2009 OPPS/ASC proposed rule requested that CMS add CPT code 52649 (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)), a new code for CY 2008, to the ASC list of covered surgical procedures. The commenters asserted that the procedure is comparable to those reported by CPT codes 52647 (Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed)) and 52648 (Laser vaporization of prostate, 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)). They believed that, like CPT codes 52647 and 52648, CPT code 52649 could be safely performed in an ASC and does not require an overnight stay. One commenter explained that the primary difference between CPT codes 52648 and 52649 is the additional amount of physician time involved for the enucleation technique.

Response: CPT code 52649 was new for CY 2008, so it was assigned interim treatment under the ASC payment system and its status was, therefore, open to comment on the CY 2008 OPPS/ASC final rule with comment period. Because CPT code 52649 was new for CY 2008, we have no physician utilization data regarding the procedure's sites-of-service. Our medical advisors continue to expect that CPT code 52649 would pose a significant risk to beneficiary safety or require an overnight stay and should be excluded from the ASC list for CY 2009. Therefore, we are excluding it from the ASC list of covered surgical procedures. However, we will reevaluate this procedure as part of our annual review of procedures that are excluded from the ASC list during development of the CY 2010 OPPS/ASC proposed rule.

Comment: One commenter requested that CMS add CPT code 57310 (Closure of urethrovaginal fistula) to the ASC list of covered surgical procedures. The commenter contended that the procedure is less complex than the procedure reported by CPT code 57320 (Closure of vesicovaginal fistula; vaginal approach), which is on the ASC list, and that the procedure would be safe for performance in ASCs and would not require an overnight stay.

Response: The utilization data for CPT code 57310 show that the procedure is performed roughly half of the time on an inpatient basis and that there is no utilization in physicians' offices or ASCs. Based on those data, in addition to the clinical judgment of our medical advisors that the procedure would be expected to pose a significant risk to beneficiary safety and require an overnight stay when performed in an ASC, we believe that CPT code 57310 should continue to be excluded from the ASC list of covered procedures for CY 2009.

Comment: One commenter, on behalf of many ASCs, requested the addition of CPT codes 64448 (Injection, anesthetic agent; femoral nerve, continuous infusion by catheter (including catheter placement) including daily management for anesthetic agent administration) and 64449 (Injection, anesthetic agent; lumbar plexus, posterior approach, continuous infusion by catheter (including catheter placement) including daily management for anesthetic agent administration) to the ASC list of covered surgical procedures for CY 2009. The commenter stated that these procedures are provided to non-Medicare patients in ASCs on a regular basis and that patients would not require care overnight.

Response: Our medical advisors examined the utilization data and available clinical information for these procedures and determined that they are appropriate for Medicare payment as covered surgical procedures in ASCs.

Although the utilization data show that the procedures are usually provided to inpatients as a component of anesthesia for an inpatient surgical procedure, such as total knee replacement, we realize that both CPT code 64448 and 64449 also may be provided as independent, primary procedures. When the procedures are the primary procedures provided to the beneficiary, we agree with the commenter that the ASC is an appropriate site-of-service. Therefore, we will assign payment indicator ''G2'' to CPT codes 64448 and 64449 for CY 2009.

Comment: As discussed further in section XI. of this final rule with comment period, commenters requested that CPT code 0184T (Excision of rectal tumor, transanal endoscopic microsurgical approach (i.e., TEMS)) be removed from the OPPS inpatient list. They also recommended that once the procedure was removed from the inpatient list, it should be added to the ASC list of covered surgical procedures because the procedure is minimally invasive and is clinically comparable to CPT code 45170 (Excision of rectal tumor, transanal approach), which is not excluded from the ASC list.

Response: As discussed in section XI. of this final rule with comment period, we consulted with our medical advisors in reevaluating CPT code 0184T for removal from the inpatient list and determined that the procedure should remain on the inpatient list. Therefore, the procedure will continue to be excluded from the ASC list.

Comment: Several commenters asked that CMS remove a number of procedures from the list of covered surgical procedures. They expressed their concern that CMS has not excluded these procedures and strongly urged CMS to remove the procedures from the list because they are not safely performed in ASCs. Specifically, one commenter asserted that CPT codes 21215 (Graft, bone; mandible (includes obtaining graft)); 40700 (Plastic repair of cleft lip/nasal deformity; primary, partial or complete, unilateral); 40701 (Plastic repair of cleft lip/nasal deformity, primary bilateral, one stage procedure); 42200 (Palatoplasty for cleft palate, soft and/or hard palate only); 42205 (Palatoplasty for cleft palate, with closure of alveolar ridge; soft tissue only); 42210 (Palatoplasty for cleft palate, with closure of alveolar ridge; with bone graft to alveolar ridge includes obtaining graft)), 42215 (Palatoplasty for cleft palate; major revision); and 42220 (Palatoplasty for cleft palate; secondary lengthening procedure) require general anesthesia and close postoperative monitoring and are often performed in the inpatient setting.

The commenters would like the procedures removed from the ASC list for a number of reasons. First, they asserted that the eight procedures are unsafe for performance in ASCs due to the need for general anesthesia and postoperative airway monitoring and reminded CMS that most of the patients who undergo these procedures are children and that very few are Medicare beneficiaries. They believed that the close monitoring of the airway postoperatively is beyond the typical ASC scope of observation. They also requested that the procedures be excluded from ASC payment because they are concerned that private insurers may misinterpret the procedures' inclusion on the ASC list as a Medicare policy that means the procedures should never be provided in the inpatient setting.

Response: We do not see a basis for removing these procedures from the ASC list. All eight of these procedures were on the list of covered surgical procedures even before CY 2007 and, to our knowledge, have been safely performed in ASCs all of that time. Our policy to not exclude a procedure from the ASC list is not an indication that a procedure should no longer be provided in other settings, including the hospital inpatient setting. We take this opportunity to reiterate two points relative to the ASC list: we make decisions regarding procedures excluded from the ASC list based on our assessments of the needs of Medicare beneficiaries; and we include on the ASC list all procedures we believe are appropriate in order to provide physicians and patients with the most choices possible for sites-of-service. We expect that physicians will consider for each individual patient which site-of-service is most appropriate. We understand that the procedures on the ASC list are sometimes more appropriately performed on an inpatient basis due to the individual's age or other clinical considerations.

After consideration of the public comments received, as discussed above, we are adopting for CY 2009 the 14 ASC covered surgical procedures and payment indicators as set out in Table 43 below.

TABLE 43—ASC COVERED SURGICAL PROCEDURES ADDED FOR CY 2009

CY 2009 HCPCS code	CY 2009 Short descriptor	Final CY 2009 ASC payment indicator
15170	Acell graft trunk/arms/legs	G2
15171	Acell graft t/arm/leg add-on	G2
15175	Acellular graft, f/n/hf/g	G2
15176	Acell graft, f/n/hf/g add-on	G2
34490	Removal of vein clot	G2
36455	Bl exchange/transfuse non-nb	G2
49324	Lap insertion perm ip cath	G2
49325	Lap insertion perm ip cath	G2
49326	Lap w/omentopexy add-on	G2
64448	N block inj fem, cont inf	G2
64449	N block inj, lumbar plexus	G2
0190T	Place intraoc radiation src	G2
0191T	Insert ant segment drain int	G2
0192T	Insert ant segment drain ext	G2

b. Covered Surgical Procedures Designated as Office-Based

(1) Background

In the August 2, 2007 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 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).

In the August 2, 2007 final rule, we identified a list of procedures as office-based after taking into account the most recently available CY 2005 volume and utilization data for each individual procedure or group of related procedures. We believed that the resulting list accurately reflected Medicare practice patterns and that the procedures were of similar complexity. In Addendum AA to that final rule, each of the office-based procedures was identified by payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated it would be paid according to the standard ASC payment methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU amount.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66840 through 66841), we finalized the temporary office-based designations of 4 procedures, while newly designating 19 procedures as permanently office-based, In addition, we designated 3 procedures reported by CPT codes 21073 (Manipulation of temporomandibular joint(s) (TMJ), therapeutic, requiring an anesthesia service (ie, general or monitored anesthesia care); 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); and 68816 (Probing of nasolacrimal duct, with or without irrigation; with transluminal balloon catheter dilation) that were new for CY 2008 as temporarily office-based on an interim basis. Those 3 temporary designations for the new CY 2008 CPT codes were open to comment during the 60-day comment period for the CY 2008 OPPS/ASC final rule with comment period. We indicated that we would respond to public comments on those designations in the CY 2009 OPPS/ASC final rule with comment period, which we do in the discussion in section XV.E.1.b.(2) of this final rule with comment period.

(2) Changes to Covered Surgical Procedures Designated as Office-Based for CY 2009

In developing the CY 2009 OPPS/ASC proposed rule, we followed our final 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 the CY 2007 utilization data and clinical characteristics for all those surgical procedures newly added for ASC payment in CY 2008 that were assigned payment indicator ''G2'' in the CY 2008 OPPS/ASC final rule with comment period.

As a result of that review, we identified the following 5 procedures that we proposed to newly designate as office-based procedures for CY 2009: CPT code 0084T (Insertion of a temporary prostatic urethral stent); CPT code 36515 (Therapeutic apheresis; with extracorporeal immunoadsorption and plasma reinfusion); CPT code 36516 (Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion); CPT code 65436 (Removal of corneal epithelium; with application of chelating agent (e.g., EDTA)); and CPT code 67505 (Retrobulbar injection; alcohol) (73 FR 41527). We proposed to make the office-based designation of CPT code 0084T temporary because we did not have adequate data upon which to base a permanent designation. We proposed to make permanent office-based designations for the remaining four procedures. The codes that we newly proposed as office-based were displayed in Table 40 of the CY 2009 OPPS/ASC proposed rule (73 FR 41527–8).

Comment: Commenters stated that CMS should not finalize any of its proposed new designations of procedures as office-based, in order to limit the exposure of the ASC payment system to the vulnerabilities of the MPFS. Further, they asserted that CMS did not provide publicly accessible data to validate the agency's assertions that the procedures proposed for temporary or permanent assignment as office-based procedures were commonly performed in physicians' offices in CY 2007. They also shared their belief that, as more procedures are designated office-based, the linkage between the ASC and OPPS ratesetting methodology would be eroded and relative weight scaling based on changes in OPPS median costs would be confounded.

Response: We continue to believe that our policy to identify low complexity procedures that are usually provided in physicians' offices is necessary and valid. We believe this is the most appropriate approach to preventing the creation of payment incentives for services to move from physicians' offices to ASCs for the many newly-covered low complexity procedures on the ASC list. Moreover, we are confident that the CY 2007 claims data, the most recent full year of volume and utilization data, is an appropriate source to inform our decisions regarding the site-of-service for procedures. Our office-based designations are based on our medical advisors' clinical judgments, utilization data for procedures that are closely related to the procedures being evaluated, and any other information that is available to us, in addition to the claims data. We post a number of supporting data files on the CMS Web site for each proposed and final rule for the annual OPPS/ASC update. Although we do not post all relevant Medicare data on the CMS Web site, Medicare claims data are available to any member of the public who chooses to purchase and use these data. Therefore, we believe that commenters have access to relevant Medicare claims and utilization data in order to conduct analyses that would assist them in evaluating all of our ASC proposals.

Regarding the commenters' assertions that increasing the number of procedures designated as office-based further erodes the linkage between the OPPS and ASC ratesetting methodologies and increases the exposure of the ASC payment system to the ''vulnerabilities of the MFPS,'' it is unclear to what vulnerabilities of MPFS the commenters are referring. However, we continue to believe that it is appropriate that ASCs be paid no more for performing office-based procedures than those procedures would be paid when performed in physicians' offices, in order to deter inappropriate

migration of these surgical procedures to ASCs based on financial considerations rather than clinical needs. Therefore, we believe it is necessary to update the office-based list of ASC covered surgical procedures annually, to account for changes in medical practice and new surgical procedures that may result in additional surgical procedures that are predominantly performed in physicians' offices.

Comment: One commenter supported the designation of CPT codes 0084T (Insertion of a temporary prostatic urethral stent) and 55876 (Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple) as office-based procedures. The commenter stated that the procedure reported by CPT code 0084T is minimally invasive and can be safely performed in the physician's office setting. The commenter also requested that CMS make permanent the office-based designation of CPT code 55876. The commenter stated that the procedure is being performed safely in the physician office setting and believed that office-based utilization is increasing.

Response: We thank the commenter for the support. However, we will maintain the temporary office-based designations for CPT codes 0084T and 55876 until we are able to evaluate more complete utilization and clinical information for those procedures. CPT Code 55876 is discussed below in more detail.

The utilization data for the procedures listed in Table 44 did not change between the proposed rule and this final rule with comment period. Therefore, after consideration of the public comments received, we are finalizing our CY 2009 proposal, without modification, to designate the procedures displayed in Table 44 as office-based for CY 2009. The office-based designation of CPT code 0084T remains temporary.

TABLE 44—CY 2009 FINAL DESIGNATIONS OF ASC COVERED SURGICAL PROCEDURES NEWLY DESIGNATED AS OFFICE-BASED

CY 2009 HCPCS code	CY 2009 short descriptor	CY 2008 ASC payment indicator	Proposed CY 2009 ASC payment indicator	Final CY 2009 ASC payment indicator
0084T	Temp prostate urethral stent	G2	R2*	R2*
36515	Apheresis, adsorp/reinfuse	G2	P2	P2
36516	Apheresis, selective	G2	P2	P2
65436	Curette/treat cornea	G2	P3	P3
67505	Inject/treat eye socket	G2	P3	P3

* If designation is temporary.

Furthermore, during the development of the CY 2009 OPPS/ASC proposed rule, we reviewed CY 2007 utilization and other information for the seven procedures with temporary office-based designations for CY 2008. Of those procedures, in the CY 2009 OPPS/ASC proposed rule, we proposed to make permanent the office-based designation for CPT code 28890 (Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia) (73 FR 41528). In response to comments on the CY 2008 OPPS/ASC proposed rule, in the CY 2008 OPPS/ASC final rule with comment period, we made the office-based designation for CPT code 28890 temporary rather than permanent as was proposed (72 FR 66839 through 66840). Although the CY 2006 utilization data available for development of the CY 2008 OPPS/ASC final rule with comment period showed that the service was provided more than 70 percent of the time in the physician's office setting, we were persuaded by commenters that providers may have been using CPT code 28890, which was new for CY 2006, erroneously to report less intensive extracorporeal shock wave procedures that would be more frequently performed in the physician's office. Our review of the CY 2007 data continues to support our designation of this procedure as office-based and thus, we believed it was appropriate to propose to make that designation permanent for CY 2009.

In the CY 2009 OPPS/ASC proposed rule, we proposed to not make permanent the office-based designations for the 6 other procedures for which the CY 2008 designations are temporary (73 FR 41528). For those procedures, we did not believe that the currently available utilization data provided an adequate basis for proposing permanent office-based designations. In our review of these six codes, we determined that it would be consistent for the office-based assignment of HCPCS code C9728 (Placement of interstitial device(s) for radiation therapy/surgery guidance (e.g., fiducial markers, dosimeter), other than prostate (any approach), single or multiple) also to be temporary. This procedure is paid under the CY 2008 ASC payment system as an office-based procedure but is analogous to CPT code 55876 (Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple), for which we proposed to maintain the temporary office-based payment indicator for CY 2009. Therefore, we also proposed to assign a temporary office-based payment indicator to HCPCS code C9728 for CY 2009. The procedures with temporary office-based status for the CY 2008 ASC payment system that we proposed to continue to temporarily designate as office-based procedures for CY 2009 were displayed in Table 40A of the CY 2009 OPPS/ASC proposed rule (73 FR 41528).

Those procedures and their CY 2009 proposed and final payment indicators are displayed in Table 45 below. All procedures for which the proposed office-based designation for CY 2009 was temporary also were indicated by an asterisk in Addendum AA to the CY 2009 OPPS/ASC proposed rule.

Comment: Commenters on the CY 2008 OPPS/ASC final rule with comment period and commenters on the CY 2009 OPPS/ASC proposed rule objected to the temporarily office-based designation for CPT code 21073 (Manipulation of temporomandibular joint(s) (TMJ), therapeutic, requiring an anesthesia service (i.e., general or monitored anesthesia care). They asserted that, because CPT code 21073 is new for CY 2008 and is not analogous, or essentially equivalent, to any previously existing code, CMS has no data upon which to base its

designation of CPT code 21073 as office-based. One commenter said that CMS bears the burden of proof in categorizing a service as office-based, especially because that categorization is permanent. Further, the commenters noted that, by definition, the procedure requires anesthesia services and they believe it is unlikely that physicians' offices would be the primary site for this service.

Response: We reexamined the utilization and clinical information available to us for this procedure. As noted by the commenters, CPT code 21073 is new for CY 2008 and, therefore, we do not have physician utilization data upon which to base designation of the procedure as office-based. However, our medical advisors continue to believe that CPT code 21073 describes a surgical procedure that they expect will be performed in physician's offices. In support of their clinical perspective are the clinical example and description of the procedure included in *CPT 2008 Changes: An Insider's View*. In that description, the patient undergoes the procedure under general anesthesia in the physician's office. However, because we have no Medicare utilization data for this service, we believe that a temporary office-based designation is most appropriate.

Comment: A commenter requested that CMS reconsider the designation of CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy) as temporarily office-based. The commenter said that, by its very nature, it is clear that the procedure is performed on premature newborns and that it would never be done in the office setting. Further, the commenter stated that, because the procedure is not as likely to be done in ASCs as in the HOPD or hospital neonatal intensive care unit, CMS should not preclude its performance in ASCs by setting a payment that is too low to cover the costs of the treatment.

Response: We reviewed our temporary designation for this code as office-based. Although we do not have data indicating physicians' office utilization, according to the clinical example published in *CPT 2008 Changes: An Insider's View*, the procedure requires only topical anesthesia and we continue to believe that, in the circumstances that the procedure is being performed on a child outside of the hospital setting, it would most likely be performed in the physicians' office. We would also point out that, at this time, the procedure has not been priced in the office and, as a result, the temporary assignment of payment indicator R2 results in payment at the fully implemented ASC rate. Therefore, we are maintaining for CY 2009 our designation of CPT code 67229 as temporarily office-based.

Comment: Commenters on the CY 2008 OPPS/ASC final rule with comment period and commenters on the CY 2009 OPPS/ASC proposed rule strongly opposed the interim designation of new CPT code 68816 (Probing of nasolacrimal duct, with or without irrigation; with transluminal balloon catheter dilation) as office-based. They stated that the procedure is not furnished in physicians' offices more than 50 percent of the time. They explained that because the typical patient is a 14-month old infant the surgical procedure reported by CPT code 68816 usually requires general anesthesia and absolutely requires the use of either the hospital outpatient or ASC setting.

Response: CPT code 68816 is a new code for CY 2008 and, as such, we do not have utilization data for review. We are persuaded by the commenters, however, that there is a need for a facility setting to perform most of these procedures and believe that it would be appropriate not to finalize our proposal to designate the procedure as office-based, even temporarily. Therefore, we are assigning payment indicator ''G2'' to CPT code 68816 for CY 2009.

After consideration of the public comments received, as displayed in Table 45, we are adopting for CY 2009 the following payment indicators for those procedures that were designated temporarily office-based for CY 2008 and for which we proposed to maintain their CY 2009 designation as temporarily office-based.

TABLE 45—FINAL CY 2009 PAYMENT INDICATORS FOR CY 2008 OFFFICE-BASED PROCEDURES FOR WHICH THEIR PROPOSED CY 2009 DESIGNATION WAS TEMPORARILY OFFICE-BASED*

CY 2009 HCPCS code	CY 2009 short descriptor	CY 2008 ASC payment indicator	Proposed CY 2009 ASC payment indicator	Final CY 2009 ASC payment indicator
0099T	Implant corneal ring	R2*	R2*	R2*
0124T	Conjunctival drug placement	R2*	R2*	R2*
21073	Mnpj of tmj w/anesthesia	P3*	P3*	P3*
55876	Place rt device/marker, pros	P3*	P3*	P3*
67229	Tr retinal les preterm inf	R2*	R2*	R2*
68816	Probe nl duct w/balloon	P3*	P3*	G2
C9728	Place device/marker, non pro	R2*	R2*	R2*

* If designation is temporary.

Displayed in Table 46 are new CY 2009 HCPCS codes (excluding renumbered codes) to which we have assigned temporary office-based payment indicators. As explained in section XV.D.1. of this final rule with comment period, we reviewed all of the newly created HCPCS codes that became available after the issuance of the CY 2009 OPPS/ASC proposed rule that will be used to report surgical procedures in CY 2009 to evaluate their appropriateness for the ASC list of covered surgical procedures. Of the 16 new CY 2009 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 three of the procedures would usually be performed in physicians' offices. However, because we had no utilization data for the procedures described by these new HCPCS codes, we made the office-based designations temporary rather than permanent and will reevaluate the procedures when data

become available. The temporary payment indicators for the three office-based procedures displayed in Table 46 are interim designations and are open to public comment during the 60-day comment period for this final rule with comment period. HCPCS codes that are new for CY 2009 are designated with an ''NI'' comment indicator in Addenda AA. We will respond to public comments on the interim designations in the CY 2010 OPPS/ASC final rule with comment period.

TABLE 46—CY 2009 PAYMENT INDICATORS FOR NEW CY 2009 HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES ASSIGNED TEMPORARY OFFICE-BASED PAYMENT INDICATORS ON AN INTERIM BASIS

CY 2009 HCPCS code	CY 2009 long descriptor	CY 2009 Interim ASC payment indicator
46930	Destruction of internal hemorrhoid(s) by thermal energy (eg, infrared coagulation, cautery, radio-frequency).	P3*
64455	Injection(s), anesthetic agent and/or steroid, plantar common digital nerve(s) (eg, Morton's neuroma).	P3*
64632	Destruction by neurolytic agent; plantar common digital nerve	P3*

* If designation is temporary.

c. Covered Surgical Procedures Designated as Device-Intensive

(1) Background

As discussed in the August 2, 2007 ASC 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 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 proposed rule (73 FR 41530). The 45 ''device-intensive'' procedures for which the modified rate calculation methodology applies in CY 2008 were displayed in Table 56 and in Addendum AA to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66843 and 66945 through 66993).

(2) Changes to List of Covered Surgical Procedures Designated as Device-Intensive for CY 2009

In the CY 2009 OPPS/ASC proposed rule (73 FR 41528 through 41529), we proposed to update the ASC list of covered surgical procedures that are eligible for payment according to the device-intensive procedure payment methodology for CY 2009, 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 CY 2007 claims data. OPPS device-dependent APCs are discussed further in section II.A.2.d.(1) of this final rule with comment period. The ASC covered surgical procedures that we proposed to designate as device-intensive and that would be subject to the device-intensive procedure payment methodology were listed in Table 41 of the CY 2009 OPPS/ASC proposed rule (73 FR 41529 through 41530). The HCPCS code, the HCPCS code short descriptor, the proposed payment indicator, the proposed CY 2009 OPPS APC assignment, and the proposed CY 2009 OPPS APC device offset percentage were also listed in Table 41 of the proposed rule. Each proposed device-intensive procedure was assigned payment indicator ''H8'' or ''J8,'' depending on whether it is subject to transitional payment, and all of these codes were included in Addendum AA to the CY 2009 OPPS/ASC proposed rule.

Comment: The commenters generally supported the continuation of a modified payment methodology for ASC covered surgical procedures designated as device-intensive. However, several commenters stated that many of the procedures CMS identifies as device-dependent under the OPPS are not treated as device-intensive under the revised ASC payment system, and that the resulting ASC payment rates proposed for these procedures are too low to ensure patient access to these procedures in the ASC setting. According to these commenters, the placement of an APC on the OPPS device-dependent list means that a significant portion of the procedure cost is not influenced by factors such as labor costs. They argued that ASC procedures that are device-dependent under the OPPS should likewise be protected from the full application of the ASC conversion factor, in order to properly account for the fixed cost of the device or implant, and recommended that CMS treat as device-intensive all ASC procedures that are assigned to an OPPS device-dependent APC.

The commenters expressed general concerns about the payment adequacy of procedures mapping to OPPS device-dependent APC 0083 (Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty); APC 0115 (Cannula/Access Device Procedures); APC 0202 (Level VII Female Reproductive Procedures); and APC 0623 (Level III Vascular Access Procedures). Some commenters asked that CMS reconsider the criteria for recognizing procedures as device-intensive for ASC payment purposes to include procedures where the OPPS device offset percentage is lower than 50 percent, while others requested that CMS add to the ASC list of device-intensive procedures those procedures that require items that would have been separately payable under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule prior to the implementation of the revised ASC payment system on January 1, 2008.

Several commenters did not request that CMS modify the methodology for designating ASC covered surgical procedures as device-intensive, but requested that specific procedures that were not included in Table 41 of the CY 2009 OPPS/ASC proposed rule (73 FR 41529 through 41530) be recognized as

device-intensive in CY 2009. Some commenters argued that the procedures described by the following codes always require the use of an auditory osseointegrated device and should be considered device-intensive for ASC payment purposes: CPT code 69714 (Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy); CPT code 69715 (Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy); CPT code 69717 (Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy); and CPT code 69718 (Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy). According to these commenters, the proposed ASC payment rate of approximately $3,086 would be inadequate to cover the device costs associated with these procedures and, therefore, would prevent ASCs from providing these services. The commenters added that these CPT codes map to device-dependent APC 0425 (Level II Arthroplasty or Implantation with Prosthesis), and that it is inconsistent for a procedure to be considered device-driven in one setting of care and not another setting of care.

Several commenters also pointed out that CPT code 19296 (Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy) and CPT code 19297 (Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy), which map to OPPS device-dependent APC 0648 (Level IV Breast Surgery), require the use of a device that has a list price that clearly exceeds 50 percent of the median costs calculated for those CPT codes and, therefore, concluded that these procedures should be added to the ASC list of device-intensive procedures.

Response: We appreciate commenters' recommendations on how we should designate procedures as device-intensive under the revised ASC payment system. In the August 2, 2007 revised ASC payment system final rule (72 FR 42508), we established that the modified payment methodology for calculating ASC payment rates for device-intensive procedures shall apply to ASC covered surgical procedures that are assigned to device-dependent APCs under the OPPS for the same calendar year, where those APCs have a device cost of greater than 50 percent of the APC cost (that is, the device offset percentage is greater than 50). We believe these criteria ensure that ASC payment rates are adequate to provide packaged payment for high cost implantable devices and ensure beneficiaries have access to these procedures in all appropriate care settings. We do not agree that we should change our criteria and treat as device-intensive all ASC services that map to OPPS device-dependent APCs, or the subset of procedures that are assigned to OPPS device-dependent APCs with device offset percentages less than 50 percent, regardless of whether those procedures require items that would have been separately payable under the DMEPOS fee schedule prior to the implementation of the revised ASC payment system on January 1, 2008. Under the modified payment methodology for ASC covered surgical procedures designated as device-intensive, we separately determine both the device payment and service payment portions of the ASC payment rate, and apply the ASC conversion factor only to the specially calculated OPPS relative payment weight for the service portion, while providing the same packaged payment for the device portion as would be made under the OPPS. The 50-percent device offset threshold is established to ensure that the ASC conversion factor is not applied to the costs of high cost implantable devices, which likely do not vary between ASCs and OPPS hospitals in the same manner service costs have been shown to vary. We believe that when device costs comprise less than 50 percent of total procedure costs, those costs are less likely to be as predictable across sites-of-service. Accordingly, we believe that it is possible for ASCs to achieve efficiencies relative to OPPS hospitals when providing those procedures, and that the application of the ASC conversion factor to the entire ASC payment weight is appropriate.

We note that, due to additional claims and revised cost report data that have become available since we issued the CY 2009 OPPS/ASC proposed rule, the OPPS device offset percentage for device-dependent APC 0425 is now greater than 50 percent. Therefore, the procedures that are on the list of ASC covered surgical procedures and assigned to this APC, including auditory osseointegrated device implantation procedures, are designated as device-intensive for ASC payment purposes for CY 2009, as shown in Table 47 below. However, the device offset percentages for APC 0083, APC 0115, APC 0202, APC 0623, and APC 0648 remain below 50 percent based on the CY 2007 claims data available for this final rule with comment period. Therefore, the surgical procedures that are assigned to these APCs under the OPPS and that are on the ASC list of covered surgical procedures are not considered to be device-intensive procedures for CY 2009 and they are not subject to the modified ASC payment methodology.

Comment: Some commenters urged CMS to move to the fully implemented transitional payment rate in CY 2009 for procedures that require implantable devices but are not designated as device-intensive. According to commenters, ASCs cannot afford to perform procedures with significant device costs for which no payment for the device is made during the transition. Commenters offered as an example the procedure described by CPT code 26535 (Arthroplasty, interphalangeal joint; each joint), which requires implantation of a prosthetic joint. Commenters noted that because the procedure does not map to a device-dependent APC and is not considered device-intensive for ASC payment purposes, the procedure would not be economically feasible to perform in the ASC setting until full implementation of the revised ASC payment rates in CY 2011. Some commenters stated that the payment rates calculated for ASC device-intensive procedures that are subject to transitional payment also are too low.

One commenter recommended that CMS exempt CPT code 51715 (Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck) from the 4-year transition and immediately adopt the ''fully implemented'' ASC payment rate in order to recognize more appropriately the procedure's device costs. The commenter calculated the OPPS device offset percentage of CPT code 51715 and found that it equals 29 percent of the CY 2009 OPPS proposed payment rate for CPT code 51715, but 68 percent of the CY 2009 ASC proposed payment rate. According to the commenter, prior to implementation of the revised ASC payment system on January 1, 2008, ASCs would have received payment for these high device costs under the DMEPOS fee schedule rather than through the ASC facility

payment for CPT code 51715. The commenter reasoned that since the devices are no longer paid separately, the procedure described by CPT code 51715 is in the same situation as a procedure code that is newly assigned to payment in the ASC setting (that is, there is no longer a relevant payment within the prior ASC system upon which to base the transition). The commenter concluded that this was an analogous case warranting the same remedy of full implementation of the ASC rate without phase-in.

Several commenters argued that CMS should not subject procedures that were on the ASC list of covered surgical procedures in CY 2007 but were rarely performed in ASCs prior to 2008 to the transitional adjustment. One commenter provided its data analysis demonstrating that CPT code 55873 (Cryosurgical ablation of the prostate (includes ultrasonic guidance for interstitial cryosurgical probe placement)) was present on three ASC claims in CY 2007, on one claim in CY 2006, and was not billed at all by ASCs in CY 2005. According to the commenters, the transitional payment for CPT code 55873 is inadequate to cover ASCs' costs of providing the procedure and will prevent beneficiaries from accessing this procedure in the ASC setting.

Response: We do not agree that we should move to the full revised ASC payment rates in CY 2009 for all ASC covered surgical procedures that may require implantable devices but are not designated as device-intensive for ASC payment purposes. As we stated in the August 2, 2007 revised ASC payment system final rule (72 FR 42520), the transition to the fully implemented revised ASC payment system should not be asymmetrical, meaning that procedures with decreasing payments under the revised payment system should not be transitioned differently from those with increasing payments. We also do not agree that procedures not designated as device-intensive that require items that would have been separately payable under the DMEPOS fee schedule prior to the implementation of the revised ASC payment system on January 1, 2008, are in the same situation as a procedure code that is newly covered in the ASC setting, and thus not subject to the transition.

As stated above, only those ASC covered surgical procedures that are assigned to OPPS device-dependent APCs and have OPPS device offset percentages greater than 50 percent are designated as device-intensive for ASC payment purposes. CPT code 26535 and CPT code 51715 are not assigned to OPPS device-dependent APCs, and thus do not meet the criteria established for designating ASC covered surgical procedures as device-intensive. Accordingly, we do not distinguish between the device and service portions of ASC payment for these procedures, and the transitional adjustment is applied to the total ASC payment rates. As established in regulation at § 416.171(c), the transitional adjustment applies to all services on the CY 2007 ASC list of covered services. We cannot make an exception for procedures, such as the one described by CPT code 55873, that were on the CY 2007 ASC list of covered services but were rarely performed in ASCs according to commenters.

We disagree with commenters that payment rates for ASC device-intensive procedures that are subject to transitional payment also are too low. Consistent with the approach under the modified payment methodology for ASC covered surgical procedures designated as device-intensive whereby we only apply the ASC conversion factor to the service payment portion of the ASC payment rate and not the device payment portion, we also apply the transition policy differentially to the device and service payment portions of the total ASC payment. While we do not subject the device payment portion of the total ASC payment for the procedure to the transition policy, we do transition the service payment portion of the total ASC payment for the procedure over the 4-year phase-in period. As described in the August 2, 2007 revised ASC payment system final rule (72 FR 42521), during each of the transition years, when the CY 2007 ASC payment rate for a device-intensive procedure that did not previously include packaged ASC payment for the implantable device itself is blended with the payment developed under the methodology of the revised ASC payment system that would otherwise package the device payment, the full device payment amount is paid to ASCs in the transition year, with blended payment determined only for the service portion of the ASC payment, for which a corresponding CY 2007 ASC payment rate exists. This specific transition approach helps ensure that ASCs receive appropriate packaged payment for implantable devices during the transition years, even though payment for such devices is generally not included in their base CY 2007 ASC payment rate.

Comment: Some commenters urged CMS not to adjust the device-or implant-related portion of ASC payment by the Medicare wage index. According to commenters, the acquisition of devices and implants occurs on a national market, and ASCs in rural areas pay approximately the same for medical devices and equipment as are facilities in more expensive labor markets. The commenters stated that CMS is underpaying device costs in markets where the wage index is low, and overpaying in markets where the wage index is high. The commenters recommended CMS use the OPPS device offset percentage where calculated for OPPS device-dependent procedures to determine what portion of the ASC payment should be excluded from wage index adjustment. For other services that are not device-dependent under the OPPS, commenters recommended CMS calculate the amount of the payment attributable to the median device cost and apply the wage index to the remainder of the payment.

Response: We do not believe it is appropriate to vary the percentage of the national payment that is wage adjusted for different services. Under the revised ASC payment system, we utilize 50 percent as the labor-related share to adjust national ASC payment rates for geographic wage differences. We apply to ASC payments the IPPS pre-floor, pre-reclassification wage index values associated with the June 2003 OMB geographic localities, as recognized under the IPPS and OPPS, in order to adjust the labor-related portion of the national ASC payment rates for geographic wage differences. Consistent with the OPPS, we apply the ASC geographic wage adjustment to the entire ASC payment rate for device-intensive procedures. MedPAC has indicated its intent to evaluate CMS' method for adjusting payments for variations in labor costs in light of differences in labor-related costs for device-implantation services. We look forward to reviewing the results of its evaluation, as well as any recommendations it may provide, regarding the OPPS or ASC wage adjustment policy.

Comment: Commenters expressed concern that the payment increase proposed for cochlear implant procedures would be insufficient to cover the true costs associated with the cochlear implant device, described by HCPCS code L8614 (Cochlear device, includes all internal and external components), and related surgical procedure, described by CPT code 69930 (Cochlear device implantation, with or without mastoidectomy), which is assigned to OPPS device-dependent APC 0259 (Level VII ENT Procedures).

In order to preserve access to this service in the ASC setting, commenters urged CMS to reconsider the CY 2009 proposed ASC payment rate of approximately $22,744 based on estimates of the selling price of the cochlear implant device as calculated using hospital invoice data supplied separately by the two leading cochlear implant manufacturers. Other commenters encouraged CMS to continue to monitor and adjust payments for cochlear implant claims including CPT code 69930 paired with HCPCS code L8614.

Response: We calculate the ASC relative payment weights using the OPPS relative weights, which are based on hospitals' costs as reported on claims and in cost reports. As discussed in section II.A.2.d.(1). of this final rule with comment period, we disagree with the commenters that it would be appropriate to use external pricing information in place of the costs derived from the claims and Medicare cost report data for APC 0259 because we believe that to do so would distort the relativity that is fundamental to the integrity of the OPPS. We do not believe it would be appropriate to deviate from our standard ratesetting methodologies, either for OPPS device-dependent APCs or ASC device-intensive procedures, based on manufacturer estimates of a particular device's selling price relative to the OPPS or ASC payment rate.

Comment: One commenter requested CMS adjust the OPPS device offset percentages for ASC device-intensive payment purposes to account for the effects of charge compression. According to the commenter, CMS should ''decompress'' the supply median costs to minimize any artificial reductions that charge compression causes in the estimate of the OPPS device offset percentages.

Response: As discussed in section II.A.1.c.(2) of this final rule with comment period, for CY 2009, we are not adopting any short-term statistical regression-based adjustments under the OPPS that would serve to ''decompress'' the median costs for procedures involving devices, or for any other procedures. Rather, we are focusing on long-term changes to Medicare cost reporting to address the effects of charge compression, including the creation of two new cost centers, Medical Supplies Charged to Patients and Implantable Devices Charged to Patients, to replace the current cost center called Supplies Charged to Patient as discussed in section II.A.1.c.(2) of this final rule with comment period. We believe that this change to how hospitals report costs for devices and supplies will improve our future estimates of costs related to high cost implantable devices, including the device offset percentages upon which we base the device portion of ASC payment rates for device-intensive procedures.

Comment: One commenter recommended that CMS adopt the OPPS concepts of pass-through payments and New Technology APCs into the ASC payment system. According to the commenter, adequate payment for newer advanced technologies in the most appropriate setting will ensure optimum care for Medicare beneficiaries.

Response: Under the revised ASC payment system, we provide separate payment at contractor-priced rates for devices that are included in device categories with pass-through status under the OPPS when the devices are an integral part of a covered surgical procedure. As discussed in section IV.A. of this final rule with comment period, 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 2009. New technology surgical procedures described by Category III CPT codes or Level II HCPCS codes that crosswalk directly or are clinically similar to established procedures already on the ASC list of covered surgical procedures, including those assigned to New Technology APCs under the OPPS, are eligible for ASC payment if we believe they would not be expected to pose a significant risk to the safety of Medicare beneficiaries and to require an overnight stay when provided in an ASC.

Under the OPPS, new technology procedures that are not eligible for pass-through payment may be assigned temporarily to a New Technology APC. Those APCs are designated by cost bands, with payment under the OPPS at the midpoint of the cost band, and were created to allow CMS to make appropriate and consistent payment for new procedures, based on their estimated costs, that are not yet reflected in OPPS claims data. This OPPS methodology provides a mechanism for timely Medicare payment for some new technologies. ASC payment for procedures assigned to New Technology APCs under the OPPS and included on the ASC list of covered surgical procedures is made at the ASC rate calculated according to the standard methodology for the ASC payment system. Thus, ASCs have the same timely access to payment for any new technology procedure that is a covered ASC surgical procedure assigned to a New Technology APC under the OPPS.

We do not believe it is necessary to implement any additional ASC-specific policies to ensure adequate payment for newer advanced technologies in the ASC setting. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66843), we believe these policies serve to appropriately incorporate payment for new technologies under the revised ASC payment system. After consideration of the public comments received, we are designating the ASC covered surgical procedures displayed in Table 47 below as device-intensive for CY 2009.

TABLE 47—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE-INTENSIVE FOR CY 2009

CY 2009 HCPCS code	CY 2009 short descriptor	Final CY 2009 ASC payment indicator	Final CY 2009 OPPS APC	CY 2009 OPPS APC title	Final CY 2009 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

TABLE 47—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE-INTENSIVE FOR CY 2009—Continued

CY 2009 HCPCS code	CY 2009 short descriptor	Final CY 2009 ASC payment indicator	Final CY 2009 OPPS APC	CY 2009 OPPS APC title	Final CY 2009 device-dependent APC offset percentage
25442	Reconstruct wrist joint	H8	0425	Level II Arthroplasty or Implantation with Prosthesis.	59
25446	Wrist replacement	H8	0425	Level II Arthroplasty or Implantation with Prosthesis.	59
27446	Revision of knee joint	J8	0681	Knee Arthroplasty	71
33206	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes.	72
33207	Insertion of heart pacemaker	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes.	72
33208	Insertion of heart pacemaker	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker.	76
33212	Insertion of pulse generator	H8	0090	Insertion/Replacement of Pacemaker Pulse Generator.	74
33213	Insertion of pulse generator	H8	0654	Insertion/Replacement of a permanent dual chamber pacemaker.	77
33214	Upgrade of pacemaker system	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker.	76
33224	Insert pacing lead & connect	J8	0418	Insertion of Left Ventricular Pacing Elect..	71
33225	Lventric pacing lead add-on	J8	0418	Insertion of Left Ventricular Pacing Elect..	71
33240	Insert pulse generator	J8	0107	Insertion of Cardioverter-Defibrillator.	89
33249	Eltrd/insert pace-defib	J8	0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads.	88
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.	59
53444	Insert tandem cuff	H8	0385	Level I Prosthetic Urological Procedures.	59
53445	Insert uro/ves nck sphincter	H8	0386	Level II Prosthetic Urological Procedures.	69
53447	Remove/replace ur sphincter	H8	0386	Level II Prosthetic Urological Procedures.	69
54400	Insert semi-rigid prosthesis	H8	0385	Level I Prosthetic Urological Procedures.	59
54401	Insert self-contd prosthesis	H8	0386	Level II Prosthetic Urological Procedures.	69
54405	Insert multi-comp penis pros	H8	0386	Level II Prosthetic Urological Procedures.	69
54410	Remove/replace penis prosth	H8	0386	Level II Prosthetic Urological Procedures.	69
54416	Remv/repl penis contain pros	H8	0386	Level II Prosthetic Urological Procedures.	69
55873	Cryoablate prostate	H8	0674	Prostate Cryoablation	59
61885	Insrt/redo neurostim 1 array	H8	0039	Level I Implantation of Neurostimulator.	84
61886	Implant neurostim arrays	H8	0315	Level III Implantation of Neurostimulator.	88
62361	Implant spine infusion pump	H8	0227	Implantation of Drug Infusion Device.	82
62362	Implant spine infusion pump	H8	0227	Implantation of Drug Infusion Device.	82
63650	Implant neuroelectrodes	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	57
63655	Implant neuroelectrodes	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	62
63685	Insrt/redo spine n generator	H8	0222	Level II Implantation of Neurostimulator.	85
64553	Implant neuroelectrodes	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	57
64555	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	57

TABLE 47—ASC COVERED SURGICAL PROCEDURES DESIGNATED AS DEVICE-INTENSIVE FOR CY 2009—Continued

CY 2009 HCPCS code	CY 2009 short descriptor	Final CY 2009 ASC payment indicator	Final CY 2009 OPPS APC	CY 2009 OPPS APC title	Final CY 2009 device-dependent APC offset percentage
64560	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	57
64561	Implant neuroelectrodes	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	57
64565	Implant neuroelectrodes	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes.	57
64573	Implant neuroelectrodes	H8	0225	Implantation of Neurostimulator Electrodes, Cranial Nerve.	62
64575	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	62
64577	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	62
64580	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	62
64581	Implant neuroelectrodes	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	62
64590	Insrt/redo pn/gastr stimul	H8	0039	Level I Implantation of Neurostimulator.	84
65770	Revise cornea with implant	H8	0293	Level V Anterior Segment Eye Procedures.	65
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	84

d. Surgical Procedures Removed From the OPPS Inpatient List for CY 2009

As discussed in section XV.C.3. of this final rule with comment period, we will evaluate all procedures at the time they are removed from the OPPS inpatient list for inclusion on the ASC list of covered surgical procedures. The final list of procedures removed from the inpatient list for CY 2009 may be found in section XI.B. of this final rule with comment period.

We evaluated each of the 12 procedures removed from the OPPS inpatient list for CY 2009. We determined that all of these procedures will be excluded from the ASC list of covered surgical procedures for CY 2009 because they may be expected to pose a significant risk to beneficiary safety in ASCs or require an overnight stay. The procedures will be evaluated again as part of our annual review of excluded surgical procedures in preparation for the CY 2010 update to the ASC payment system.

2. Covered Ancillary Services

In the CY 2009 OPPS/ASC proposed rule (73 FR 41530), we proposed to update the ASC list of covered ancillary services to reflect the services' proposed separate payment status under the CY 2009 OPPS. Maintaining consistency with the OPPS resulted in proposed changes to ASC payment indicators because some covered ancillary services that are paid separately under the revised ASC payment system in CY 2008 were proposed for packaged status under the OPPS for CY 2009. Comment indicator ''CH,'' as discussed in section XV.F. of the CY 2009 OPPS/ASC proposed rule (73 FR 41537), was used in Addendum BB to that proposed rule to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect, for example, our proposal to package payment for the service under the CY 2009 ASC payment system consistent with its proposed treatment under the CY 2009 OPPS.

Comment: Several commenters requested that CMS remove CPT codes 77520 (Proton treatment delivery; simple, without compensation); 77522 (Proton treatment delivery; simple, with compensation); 77523 (Proton treatment delivery; intermediate); and 77525 (Proton treatment delivery; complex) from the list of covered ancillary services. The reasons the commenters provided for this request are that proton beam therapy is never provided integral to a surgical procedure and, as such, would never be eligible for payment in ASCs and providing proton beam therapy requires a much larger capital investment than would be feasible for ASCs. The commenters believed that because the services would not be provided in ASCs, including them on the list of covered ancillary services was unnecessary, and that having ASC rates published for the services could result in confusion on the part of other payers who mistakenly believe that the published Medicare ASC rates for proton beam therapy are actually used by Medicare to pay for those services when they are performed alone.

Response: While we understand the commenters' concerns, our policy is to include as covered ancillary services all

procedures with CPT codes in the radiology range of CPT, specifically CPT codes 70000 through 79999 (72 FR 42497). We do not evaluate those services to determine whether or not they would ever be provided in ASCs integral to covered surgical procedures. By definition, CPT codes 77520, 77522, 77523 and 77525 are included as covered ancillary services and, therefore, we are not removing proton beam therapy codes from that list for CY 2009.

Comment: Several commenters requested that HCPCS codes G0339 (Image guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session, or first session of fractionated treatment) and G0340 (Image guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment); and CPT codes 0071T (Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue) and 0072T (Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue) be removed from the ASC list of covered ancillary services and instead be included on the ASC list of covered surgical procedures. The commenters stated that these services are surgical procedures.

One commenter asserted that the procedures described by HCPCS codes G0339 and G0340 require joint participation of a surgeon and a radiation oncologist and treat tumors that have not responded to traditional radiation therapy. As procedures that can be provided without a covered surgical procedure, the commenter requested that CMS allow the procedures to be eligible for separate payment in ASCs as covered surgical procedures. Similarly, the commenter contended that the procedures reported by CPT codes 0071T and 0072T also are noninvasive surgical procedures that should be payable as covered surgical procedures in ASCs. The commenter noted that CMS defined those two procedures as noninvasive surgical procedures in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66710).

Response: While we originally included the services described by CPT codes 0071T and 0072T on the list of covered ancillary services because of the similarities between these services and stereotactic radiosurgery services and, although they are assigned to the same APCs under the OPPS as stereotactic radiosurgery services, we agree with the commenter that they are not sufficiently similar to services in the radiology range of CPT codes to be placed on the list of covered ancillary services. Therefore, we are not including them in Addendum BB to this final rule with comment period.

We define surgical procedures as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to ASC covered surgical procedures (72 FR 42478). Because Category III CPT codes 0071T and 0072T do not directly crosswalk and are not clinically similar to any ASC covered surgical procedures, we are not placing them on the list of ASC covered surgical procedures. Therefore, we are not including them in Addendum AA to this final rule with comment period.

We do not agree with the commenters that G0339 and G0340 represent surgical procedures. These HCPCS codes were developed for reporting stereotactic radiosurgery services under the OPPS and crosswalk directly to CPT codes in the radiology range of CPT. As such, we are not removing HCPCS codes G0339 and G0340 from the ASC list of covered ancillary services and we are not adding them to the list of covered surgical procedures. These HCPCS codes are included in Addendum BB to this final rule with comment period.

All CY 2009 ASC covered ancillary services and their payment indicators for CY 2009 are included in Addendum BB to this final rule with comment period.

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

1. Payment for Covered Surgical Procedures

a. Background

Our final payment policy for covered surgical procedures under the revised ASC payment system is described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). In that rule, we updated the CY 2008 rates for covered surgical procedures with payment indicators of ''A2,'' ''G2,'' ''H8,''and ''J8'' using CY 2006 data, consistent with the CY 2008 OPPS update. We also 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 2008 rate for each of the office-based procedures, calculated according to the standard methodology of the revised ASC payment system to the MPFS nonfacility PE RVU amount, to determine which was the lower payment amount that, therefore, would be the payment for the procedure according to the final policy of the revised ASC payment system (see § 416.171(d)).

Subsequent to publication of that rule, the Congress enacted the Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173. That law required changes to the rates paid under the MPFS for the first 6 months of CY 2008, and therefore, the ASC rates for some office-based procedures were also affected. We revised the CY 2008 ASC payment rates and made them available by posting them to the CMS Web site at: *http://www.cms.hhs.gov/ASCPayment/*.

Subsequent to publication of the CY 2009 OPPS/ASC proposed rule, section 131 of the MIPPA, Public Law 110–275, restored MPFS payments to the levels in effect prior to July 1, 2008 for the remainder of CY 2008 and increased the update to the conversion factor for the MPFS to 1.1 percent for CY 2009. Therefore, the ASC rates for some office-based procedures and covered ancillary radiology services for the second half of CY 2008 were affected, and the CY 2009 conversion factor increase for the MPFS also affects CY 2009 ASC payments for certain of these services.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2009

In the CY 2009 OPPS/ASC proposed rule (73 FR 41530), we proposed CY 2009 payment rates for procedures with payment indicator ''G2'' that were calculated according to the standard methodology of multiplying the proposed CY 2009 ASC relative payment weight for the procedure by the proposed CY 2009 ASC conversion factor (72 FR 42492 through 42493). Also, according to our established policy, we proposed CY 2009 payments for procedures subject to the transitional payment methodology (payment indicators ''A2'' and ''H8'') using a blend of 50 percent of the proposed CY 2009 ASC rate calculated according to the standard or device-intensive methodology, respectively, and 50 percent of the CY 2007 ASC payment rate (72 FR 42520 through 42521).

We proposed payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') and device-intensive procedures not subject to transitional payment (payment indicator ''J8'') calculated according to our established policies (72 FR 42504 and 42511). Thus, we proposed to update

the payment amounts for device-intensive procedures based on the CY 2009 OPPS proposal that reflected updated OPPS claims data and to make payment for office-based procedures at the lesser of the proposed CY 2009 MPFS nonfacility PE RVU amount or the CY 2009 ASC payment amount calculated according to the standard methodology.

Comment: Several commenters requested that CMS provide a higher ASC payment for the procedure reported by CPT code 0192T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir; external approach). Commenters stated that the proposed ASC payment rate was inadequate to cover the cost of the device and, therefore, ASCs would not be able to provide the procedures.

Response: As discussed fully in section III.A.2. of this final rule with comment period, we are reassigning CPT code 0192T to APC 0673 (Level IV Anterior Segment Eye Procedures) from APC 0234 (Level III Anterior Segment Eye Procedures), where it was proposed for assignment under the CY 2009 OPPS. This code was first implemented in July 2008, so is not subject to the transition under the ASC payment system. APC 0673 has a higher OPPS payment rate for CY 2009 than the proposed OPPS payment and, therefore, the final CY 2009 ASC payment is also higher than the proposed ASC rate. We believe that the CY 2009 ASC payment is appropriate and ensures access to this procedure for Medicare beneficiaries in ASCs.

Comment: One commenter was concerned about the proposed payment for HCPCS code G0393 (Transluminal balloon angioplasty, percutaneous; for maintenance of hemodialysis access, arteriovenous fistula or graft; venous). The commenter requested that CMS correct the payment rate for G0393 because the commenter believed it should be equal to the ASC payment for CPT code 35476 (Transluminal balloon angioplasty, percutaneous; venous). The commenter noted that in past regulations CMS crosswalked HCPCS code G0393 to that CPT code.

Response: As discussed in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68168), we created HCPCS codes G0392 (Transluminal balloon angioplasty, percutaneous; for maintenance of hemodialysis access, Arteriovenous fistula or graft; arterial) and G0393 in order to make those angioplasty procedures for arteriovenous fistulae maintenance available for Medicare payment in ASCs. At that time, the only codes available to report the procedures were CPT codes 35475 (Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel) and 35476, which were excluded from the ASC list at that time. The two new HCPCS G-codes specifically described arterial and venous angioplasty procedures to maintain hemodialysis access through arteriovenous fistulae or grafts for dialysis patients.

Subsequently, in response to comments, we added CPT code 35476 to the ASC list of covered surgical procedures in our CY 2008 final rule with comment period (72 FR 66838). HCPCS code G0393 and CPT code 35476 have the same CY 2009 OPPS payment because they are both assigned to the same APC, APC 0083 (Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty).

Although HCPCS code G0393 was created as an alternative to CPT code 35476 for some clinical situations, it was added to the ASC list in CY 2007 and is, therefore, subject to the ASC transitional payment methodology. In contrast, CPT code 35476 was added to the ASC list CY 2008 and is paid according to the standard ASC revised rate calculation methodology. Consequently, the ASC payment rates for the two procedures cannot be the same in CY 2009.

Comment: Commenters suggested that CMS abandon the office-based procedure payment policy. Their reasons for making this suggestion include a belief that CMS does not need the policy to avoid creating a payment incentive for procedures often furnished in physicians' offices to migrate to ASCs. They also believed that implementation of the payment caps is, in fact, creating payment incentives for the affected procedures to migrate to more expensive and less efficient HOPDs. They contended that CMS has overestimated the likelihood that procedures usually furnished in physicians' offices would migrate to ASCs if there are no payment limits in place. They asserted that physicians should be able to make the decision about the site-of-service based on the individual beneficiary's circumstances and that the payment limits instituted by CMS for office-based procedures interfere with that patient-physician decision-making because the rates for procedures that are capped at the nonfacility PE RVU amount are often too low to support performance of the procedure in an ASC. Thus, they argued that the policy to cap payment for some procedures effectively removes the ASC as an option for the beneficiary's care. The commenters were concerned that Medicare has not fully considered the consequences of this payment policy. They believed that in addition to limiting beneficiary access to ASCs as a site for service, this policy will result in higher Medicare costs due to the ''reverse migration'' of cases that could have been performed in efficient and lower cost ASCs migrating to more costly HOPDs.

Response: As noted by the commenters, we implemented the payment policy for office-based procedures to mitigate potentially inappropriate migration of services from the physicians' office setting to the ASC. Contrary to the commenters' beliefs that the CMS actuarial estimates for expected migration of procedures from physicians' offices to ASCs are exaggerated, our experience indicates that payment differentials do have a significant effect on practice patterns. We continue to believe the policy is appropriate in light of the many low complexity procedures we have added to the ASC list under the revised payment system. Further, we note that, prior to the revised payment system, procedures that were commonly performed in physicians' offices were excluded from the ASC list. Our policy under the revised payment system results in Medicare payment for many of those previously-excluded procedures at the full revised ASC payment rate, without a transition. We view our policy to make payment to ASCs for many of these procedures that were previously excluded as an important step in expanding the choices of sites for care available to physicians and beneficiaries. In addition, we do not view our policy to limit payment for the least complex procedures that are commonly provided in physicians' offices as a loss for ASCs. In contrast to the prior ASC payment system, our current policy provides an ASC payment for the procedures and we believe that amount is appropriate.

As discussed fully in the August 2, 2007 final rule for the revised ASC payment system (72 FR 42521 through 42535), we believe we gave full consideration to all aspects of our final payment policies for the revised ASC payment system. Our policies related to office-based procedures were adopted to avoid creating incentives for migration of surgical procedures from physicians' offices to ASCs. The low complexity procedures that were on the CY 2007 ASC list of covered surgical procedures are performed, on average, 17 percent of the time in ASCs. We expected that with the payment limits on office-based procedures, the newly added low complexity procedures would have

similar utilization patterns. Each year as we develop our proposed and final updates to the payment system, we will continue to evaluate the effects of our payment policies on ASCs, including the utilization patterns of low complexity procedures paid under the revised ASC poayment system.

Comment: Several commenters recommended that if CMS chooses not to abandon the policy to designate certain procedures as office-based and subject to payment limits, that it should modify its policy. Included in the recommended modifications to the policy related to office-based procedures, commenters suggested the following:

- Increase the utilization threshold to some level greater than 50 percent to identify office-based procedures. Although no commenters recommended an alternate threshold as a criterion for determining that a procedure is office-based, they did suggest that the threshold should be higher than 50 percent and that it should be reevaluated periodically.
- Consider utilization variation over multiple years and across geographic areas. The commenters recommended that CMS consider utilization data from multiple years and from different geographic regions to account for variability in physicians' office utilization across states for procedures. One commenter asserted that CMS' reliance on national averages to gauge practice patterns was a weakness of the policy and that the variations the commenter found across States are an indication that the payment caps might not be an effective tool for influencing site selection for surgery because many factors, such as the number of ASCs in the area, influence the site-of-service decision. With regard to fluctuations in site-of-service utilization over time, the commenter believed that the year-to-year variation reflects significant volatility and CMS' policy to make the office-based designation permanent ignores that finding. Further, the commenter asserted that the Medicare Part B claims data that CMS uses to evaluate site-of-service utilization is not a sound approach because the data are flawed.
- Discontinue use of temporary office-based designations. Commenters suggested that CMS discontinue use of temporary office-based designations because they believed that CMS usually assigns temporary designations to procedures for which there is no utilization data and that CMS should not make a determination for those procedures until some data become available. In addition, some commenters expressed frustration that the temporary designations may remain in place for years and, as such, are not really temporary. Further, payment for the procedures with temporary status is subject to the payment limits.
- Reevaluate the office-based procedures periodically so that the designation as office-based is not permanent. Several commenters did not believe it was fair to make office-based designations permanent because the policy may compromise physicians' ability to make appropriate changes in their practices as new technology and other advances become available. They urged CMS to reevaluate the procedures periodically to ensure that the designations as office-based reflect practice patterns over time.
- Limit the reduction in payment for office-based procedures and do not base payment limit on the MPFS. A few commenters asserted that CMS' policy to cap payment for office-based ASC procedures at the MPFS amount is flawed because the policy results in fluctuations in the ASC relative weights for those procedures based both on the PE RVU values and the MPFS conversion factor, both of which may vary from year to year. Rather, they believed that all ASC relative payment weights should be based on OPPS relative payment weights.

Response: We selected 50 percent as the physicians' office utilization threshold because we intended to make new ASC procedures that are usually (greater than 50 percent of the time) provided in physicians' offices subject to the payment limits. However, our decisions regarding office-based status are not entirely based on the utilization data. Physicians' office utilization is an important aspect of our evaluation but so are the volume of procedures, the clinical characteristics of procedures, and the characteristics and utilization of related and similar procedures. We continue to believe that a threshold of 50 percent is the most appropriate threshold to identify those surgical procedures that are commonly performed in physicians' offices, specifically more than half of the time. We believe that adoption of a threshold higher than 50 percent would result in ASC payment for low complexity procedures at ASC rates that could encourage migration of these procedures from physicians' offices to ASCs, even in cases where the less costly office setting was clinically appropriate.

We do not agree with the commenters' recommendations that we should consider multiple years of utilization data and variation in utilization across geographic areas to determine office-based status for each procedure. There are cases in which we do look at multiple years of utilization data in determining whether or not a procedure is office-based, such as for very low volume procedures, but that is not necessary for most procedures. Although the commenters asserted that there is significant volatility in the year-to-year utilization data for surgical procedures, we do not agree that is the case. Generally, Medicare Part B claims data reflect relatively stable site-of-service utilization across years, and we continue to see increasing physician's office utilization of new low complexity procedures rather than decreasing levels.

We believe that our national policy should be guided by national data and not subject to the uncertainties of local practice patterns that may depend more on the availability of certain types of providers or suppliers in communities than the care needs of Medicare beneficiaries. Medicare is a national program and our policies are designed to ensure that all Medicare beneficiaries receive the same benefits and the same high quality care regardless of where they reside or travel in the United States. It would be inappropriate to institute different policies related to covered services by geographic area.

As stated above, we use physicians' claims data, the clinical judgments of our medical advisors, and any other relevant information that is available to make our determination that a procedure is office-based. We believe that our data are reliable, and we will continue to rely on the claims data as one source of information to evaluate the sites-of-service for surgical procedures.

We apply the temporary designation when our clinical evaluation suggests that the procedure is of a complexity level such that performance in the physician's office is the most appropriate and likely site for care, but there are little or no data or experience so we are not certain that the procedure will be provided most of the time in physicians' offices. We also handle the designation of office-based status, including temporary status, through the annual notice and comment rulemaking process to allow for public input into those determinations.

Once we have completed the process and designated ASC covered surgical procedures as office-based, we are confident that our permanent office-based designations are appropriate and that the resulting payment amounts are appropriate for providing the service in ASCs if a facility site is required for a particular beneficiary. We expect that it

would be extremely rare for procedures that were usually provided in physicians' offices to become more complex procedures that require facility settings due to new technology or other advances, while the CPT coding for such procedures is unchanged. In general, advances in technology and medical practice have historically led to less-invasive surgical methods and allowed for less-intensive sites-of-service. We do not see a need for the periodic reevaluation of all office-based designations.

Finally, there are several instances in which Medicare payment systems use values and relative weights that are external, or from other systems, to make payment. We believe that making payment to ASCs at the nonfacility PE RVU amount for procedures that have been priced specifically for the physicians' office setting is entirely appropriate given our intention to not create an incentive for those procedures to migrate to another setting. Further, we believe that limiting the ASC payment for office-based procedures to the physician's office rate provides appropriate payment to the ASC for those procedures when an ASC setting is necessary for the beneficiary's care.

Comment: One commenter requested that the CY 2009 ASC payment rate for CPT code 55876 (Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple) be revised to be consistent with the payment for HCPCS code C9728 (Placement of interstitial devices(s) for radiation therapy/surgery guidance (eg, fiducial markers, dosimeter), other than prostate (any approach), single or multiple) because the procedures are analogous to one another.

Response: We proposed to continue the temporary office-based designation for CPT code 55876 and to designate HCPCS code C9728 as temporarily office-based because the codes are clinically similar, but correspond to different anatomic regions of the body. However, HCPCS code C9728 has not been priced for performance in physicians' offices and, therefore, is assigned temporary office-based payment indicator ''R2,'' resulting in ASC payment at the rate calculated according to the standard ASC ratesetting methodology. Conversely, CPT code 55876 does have a nonfacility PE RVU amount and, because that amount is less than the ASC rate, payment for CPT code 55876 is made at the nonfacility PE RVU amount for the procedure.

We understand the commenter's desire for consistency, but we believe that our designation of the procedures as temporarily office-based is appropriate and we do not assign nonfacility PE RVUs to HCPCS C-codes which are not recognized for payment under the MPFS. We do not believe the payment differential between the two procedures provides sufficient justification for changing the payment indicator for CPT code 55876 so that its CY 2009 payment amount would be equal to that for HCPCS code C9728.

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

Under § 416.179, our ASC policy with regard to payment for costly devices implanted in ASCs at no cost or with full or partial credit is consistent with the OPPS policy. The CY 2009 OPPS APCs and devices subject to the adjustment policy are discussed in section IV.B.2. of this final rule with comment period. The ASC policy includes adoption of the OPPS policy for reduced payment to providers when a specified device is furnished without cost or with full 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. Specifically, as we described in the CY 2008 OPPS/ASC final rule with comment period, when a procedure provided in CY 2008 that was listed in Table 58 of the CY 2008 OPPS/ASC final rule with comment period was performed in an ASC and the case involved implantation of a no cost or full credit device listed in Table 59 of the final rule with comment period, the ASC must report the HCPCS ''FB'' modifier on the line with the covered surgical procedure code to indicate that an implantable device in Table 59 was furnished without cost. The contractor reduces 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 a full credit (72 FR 66845). We 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. The reduction of ASC payment in this circumstance was necessary to pay appropriately for the covered surgical procedure being furnished by the ASC.

Consistent with the OPPS policy, we also adopted an ASC payment policy for certain procedures involving partial credit for a specified device. Specifically, as we explained in the CY 2008 OPPS/ASC final rule with comment period, we reduce the payment for implantation procedures listed in Table 58 of the CY 2008 OPPS/ASC final rule with comment period by one half of the device offset amount that would be applied if a device were 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 (72 FR 66846). In CY 2008, ASCs must append the modifier ''FC'' to the HCPCS code for a surgical procedure listed in Table 58 of the CY 2008 OPPS/ASC final rule with comment period when the facility received a partial credit of 50 percent or more of the cost of a device listed in Table 59. In order to report that they received a partial credit of 50 percent or more of the cost of a new device, ASCs had 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 was 50 percent or more of the cost of the replacement device. Beneficiary coinsurance was based on the reduced payment amount.

Consistent with the OPPS, we proposed to update the list of ASC device-intensive procedures that would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2009. Table 42 of the CY 2009 OPPS/ASC proposed rule displayed the ASC covered implantation procedures and their payment indicators that we proposed would be subject to the no cost/full credit and partial credit device adjustment policy for CY 2009. Specifically, when a procedure that was listed in Table 42 of the proposed rule is performed in an ASC and the case involves implantation of a no cost/full credit device, or a partial credit device for which the ASC received at least a 50 percent partial credit, and the device was listed in Table 43 of the proposed rule, the ASC would report the HCPCS ''FB'' or ''FC'' modifier, as appropriate, on the line with the covered surgical procedure code. The procedures listed in Table 42 were those ASC covered device-intensive procedures assigned to APCs under the OPPS to which the policy would apply. We did not propose to apply this policy to the procedures

and devices associated with APCs 0425 (Level II Arthroplasty or Implantation with Prosthesis) and 0648 (Level IV Breast Surgery), which were proposed for inclusion in the OPPS no cost/full credit and partial credit device adjustment policy for CY 2009, because ASC covered procedures assigned to these two APCs under the OPPS did not qualify for payment as ASC covered device-intensive surgical procedures (that is, their estimated device offset percentages were less than 50 percent based on partial year data available for the proposed rule).

Comment: One commenter expressed support for the continuation of the no cost/full credit and partial credit device adjustment policy for ASCs in CY 2009.

Response: We appreciate the commenter's support of the no cost/full credit and partial credit device adjustment policy.

For CY 2009, we will reduce the payment for device implantation procedures listed in Table 48 below by the full device offset amount for no cost/full credit cases. ASCs must append the modifier ''FB'' to the HCPCS procedure code when the device furnished without cost or with full credit is listed in Table 49, below, and the associated implantation procedure code is listed in Table 48. In addition, for CY 2009, we will reduce the payment for implantation procedures listed in Table 48 by one half of the device offset amount that would be applied if a device were provided at no cost or with full credit, if the credit to the ASC is 50 percent or more of the device cost. If the ASC receives a partial credit of 50 percent or more of the cost of a device listed in Table 49, the ASC must append the modifier ''FC'' to the associated implantation procedure code if the procedure is listed in Table 48. We are adding procedures assigned to APC 0425 and their associated devices to Tables 48 and 49, respectively, because these procedures now qualify for ASC payment as device-intensive procedures based on updated claims and cost report data, as described in section XV.E.1.c. of this final rule with comment period.

TABLE 48—CY 2009 PROCEDURES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY APPLIES

CY 2009 HCPCS code	CY 2009 Short descriptor	Final CY 2009 ASC payment indicator	Final CY 2009 OPPS APC	CY 2009 OPPS APC Title	Final CY 2009 OPPS full offset percentage	Final CY 2009 OPPS partial 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	0681	Knee Arthroplasty	71	35
33206	Insertion of heart pacemaker.	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes.	72	36
33207	Insertion of heart pacemaker.	J8	0089	Insertion/Replacement of Permanent Pacemaker and Electrodes.	72	36
33208	Insertion of heart pacemaker.	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker.	76	38
33212	Insertion of pulse generator.	H8	0090	Insertion/Replacement of Pacemaker Pulse Generator.	74	37
33213	Insertion of pulse generator.	H8	0654	Insertion/Replacement of a permanent dual chamber pacemaker.	77	38
33214	Upgrade of pacemaker system.	J8	0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker.	76	38
33224	Insert pacing lead & connect.	J8	0418	Insertion of Left Ventricular Pacing Elect.	71	36
33225	Lventric pacing lead add-on.	J8	0418	Insertion of Left Ventricular Pacing Elect.	71	36
33240	Insert pulse generator.	J8	0107	Insertion of Cardioverter-Defibrillator.	89	45
33249	Eltrd/insert pacedefib.	J8	0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads.	88	44
33282	Implant pat-active ht record.	J8	0680	Insertion of Patient Activated Event Recorders.	71	36
53440	Male sling procedure.	H8	0385	Level I Prosthetic Urological Procedures.	59	29
53444	Insert tandem cuff	H8	0385	Level I Prosthetic Urological Procedures.	59	29

TABLE 48—CY 2009 PROCEDURES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY APPLIES—Continued

CY 2009 HCPCS code	CY 2009 Short descriptor	Final CY 2009 ASC payment indicator	Final CY 2009 OPPS APC	CY 2009 OPPS APC Title	Final CY 2009 OPPS full offset percentage	Final CY 2009 OPPS partial offset percentage
53445	Insert uro/ves nck sphincter.	H8	0386	Level II Prosthetic Urological Procedures.	69	34
53447	Remove/replace ur sphincter.	H8	0386	Level II Prosthetic Urological Procedures.	69	34
54400	Insert semi-rigid prosthesis.	H8	0385	Level I Prosthetic Urological Procedures.	59	29
54401	Insert self-contd prosthesis.	H8	0386	Level II Prosthetic Urological Procedures.	69	34
54405	Insert multi-comp penis pros.	H8	0386	Level II Prosthetic Urological Procedures.	69	34
54410	Remove/replace penis prosth.	H8	0386	Level II Prosthetic Urological Procedures.	69	34
54416	Remv/repl penis contain pros.	H8	0386	Level II Prosthetic Urological Procedures.	69	34
61885	Insrt/redo neurostim 1 array.	H8	0039	Level I Implantation of Neurostimulator.	84	42
61886	Implant neurostim arrays.	H8	0315	Level III Implantation of Neurostimulator.	88	44
62361	Implant spine infusion pump.	H8	0227	Implantation of Drug Infusion Device.	82	41
62362	Implant spine infusion pump.	H8	0227	Implantation of Drug Infusion Device.	82	41
63650	Implant neuroelectrodes.	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve.	57	29
63655	Implant neuroelectrodes.	J8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	62	31
63685	Insrt/redo spine n generator.	H8	0222	Level II Implantation of Neurostimulator.	85	42
64553	Implant neuroelectrodes.	H8	0040	Implantation of Neurostimulator Electrodes, Cranial Nerve.	57	29
64555	Implant neuroelectrodes.	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve.	57	29
64560	Implant neuroelectrodes.	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve.	57	29
64561	Implant neuroelectrodes.	H8	0040	Percutaneous Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve.	57	29
64565	Implant neuroelectrodes.	J8	0040	Percutaneous Implantation of Neurostimulator Electrodes, Excluding Cranial Nerve.	57	29
64573	Implant neuroelectrodes.	H8	0225	Implantation of Neurostimulator Electrodes, Cranial Nerve.	62	31
64575	Implant neuroelectrodes.	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	62	31
64577	Implant neuroelectrodes.	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	62	31
64580	Implant neuroelectrodes.	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	62	31
64581	Implant neuroelectrodes.	H8	0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr.	62	31
64590	Insrt/redo pn/gastr stimul.	H8	0039	Level I Implantation of Neurostimulator.	84	42
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

TABLE 48—CY 2009 PROCEDURES TO WHICH THE NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICE ADJUSTMENT POLICY APPLIES—Continued

CY 2009 HCPCS code	CY 2009 Short descriptor	Final CY 2009 ASC payment indicator	Final CY 2009 OPPS APC	CY 2009 OPPS APC Title	Final CY 2009 OPPS full offset percentage	Final CY 2009 OPPS partial offset percentage
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	84	42

TABLE 49—DEVICES FOR WHICH THE "FB" OR "FC" MODIFIER MUST BE REPORTED WITH THE PROCEDURE CODE WHEN FURNISHED AT NO COST OR WITH FULL OR PARTIAL CREDIT

CY 2009 Device HCPCS code	CY 2009 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.
L8690	Aud osseo dev, int/ext comp.

2. Payment for Covered Ancillary Services

a. Background

Our final CY 2008 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 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 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 nonfacility PE RVU (or technical component) amount or the rate calculated according to the standard ASC payment methodology (72 FR 42497). In all cases, ancillary services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare. As noted in section XV.D.1.a. of the CY 2009 OPPS/ASC proposed rule (73 FR 41530), changes were made to the MPFS payment rates for the period of January 1, 2008 through June 30, 2008 as a result of the enactment of the Medicare, Medicaid, and SCHIP Extension Act of 2007. In addition to changing the ASC payment rates for some office-based procedures, those changes also affected the ASC rates for some covered ancillary radiology services for the first 6 months of CY 2008.

ASC payment policy for brachytherapy sources generally mirrors the payment policy under the OPPS. We finalized our policy 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 in the CY 2008 OPPS/ASC final rule with comment period (72 FR 42499). Subsequent to publication of that rule, section 106 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 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 MIPPA amended section 1833(t)(16)(C) of the Act (as amended by section 106 of the Medicare, Medicaid, and SCHIP Extension Act of 2007) 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 will continue to be paid at contractor-priced rates for brachytherapy sources provided in ASCs 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). 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 CY 2009 OPPS/ASC final rule with comment period, 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 2009.

b. Payment for Covered Ancillary Services for CY 2009

In the CY 2009 OPPS/ASC proposed rule, for CY 2009, we proposed to update the ASC payment rates and make changes to payment indicators as necessary in order to maintain consistency between the OPPS and ASC payment systems regarding the packaged or separately payable status of services and the proposed CY 2009 OPPS and ASC payment rates (73 FR

41530). The proposed CY 2009 OPPS payment methodologies for separately payable drugs and biologicals and brachytherapy sources were discussed in sections V. and VII. of the CY 2009 OPPS/ASC proposed rule, respectively (73 FR 41480 and 41500), and the CY 2009 ASC payment rates for those services were proposed to equal the proposed CY 2009 OPPS rates. In Addendum BB to the CY 2009 OPPS/ASC proposed rule, we indicated whether the proposed CY 2009 payment rate for radiology services was based on the MPFS PE RVU amount or the standard ASC payment calculation. Thus, the proposed CY 2009 payment indicator for a covered radiology service could differ from its CY 2008 payment indicator based on packaging changes under the OPPS or the comparison of the CY 2009 proposed MPFS nonfacility PE RVU amount to the CY 2009 ASC payment rate calculated according to the standard methodology. Services that we proposed to pay based on the standard ASC rate methodology were 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 payment is based on the MPFS PE RVU amount were assigned payment indicator ''Z3'' (Radiology service paid separately when provided integral to a surgical procedure on ASC list; payment based on MPFS nonfacility PE RVUs).

Covered ancillary services and their proposed payment indicators were listed in Addendum BB to the CY 2009 OPPS/ASC proposed rule.

Comment: One commenter expressed concern that payments for certain radiological services commonly provided to patients with end-stage renal disease (ESRD) are packaged into payment for surgical procedures under the ASC payment system. They requested that 11 of those services be paid separately in ASCs and asked CMS to reexamine the packaging for the radiological services displayed below.

HCPCS code	Long descriptor	Proposed CY 2009 OPPS status indicator	Proposed CY 2009 ASC payment indicator
75710	Angiography, extremity, unilateral, radiological supervision and interpretation	Q2	N1.
75790	Angiography, arteriovenous shunt (e.g., dialysis patient), radiological supervision and interpretation.	Q2	N1.
75798	Not a valid CPT code	N/A	N/A.
75820	Venography, extremity, unilateral, radiological supervision and interpretation	Q2	N1.
75898	Angiography through existing catheter for follow-up study for transcatheter therapy, embolization or infusion.	Q1	N1.
75902	Mechanical removal of intraluminal (intracatheter) obstructive material from central venous device through device lumen, radiologic supervision and interpretation.	N	N1.
75962	Transluminal balloon angioplasty, peripheral artery, radiological supervision and interpretation.	Q2	N1.
75984	Change of percutaneous tube or drainage catheter with contrast monitoring (e.g., genitourinary system, abscess), radiological supervision and interpretation.	N	N1.
76937	Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting.	N	N1.
77011	Computed tomography guidance for stereotactic localization	N	N1.
78827	Not a valid CPT code	N/A	N/A.

The commenter expressed concern that packaging payment for these services limits full access to services for ESRD patients for the repair and maintenance of vascular access. The commenter recommended that CMS give particular attention to the packaged status of CPT codes 75710, 75790, 75962 and 75798 because they are commonly used for vascular access procedures and are critical to beneficiaries living with ESRD.

The commenter also expressed support for an APC Panel recommendation to delay packaging under the OPPS until analyses can be performed to determine the impact on beneficiaries and the viability of ASCs providing these services.

Response: We continue to believe that packaging payment for those ancillary radiology services integral to surgical procedures that would be packaged under the OPPS in an HOPD is appropriate under the revised ASC payment system. This policy is aligned with the recommendation of the Practicing Physicians Advisory Council (PPAC) to apply payment policies uniformly in the ASC and HOPD settings. It also maintains comparable payment bundles under the OPPS and the revised ASC payment system, consistent with the recommendation of MedPAC to maintain consistent payment bundles under both payment systems. Our ASC payment policy would not permit separate payment for the radiology procedures discussed by the commenter when they are provided integral to covered surgical procedures (the only case in which they would be covered and paid to the ASC), just as these same radiology services would not be paid separately under the OPPS if they accompanied a surgical procedure.

The APC Panel did make a recommendation during its August 2008 meeting for the OPPS regarding packaging for radiation therapy guidance services. The APC Panel recommended that CMS pay separately for radiation therapy guidance for 2 years and then reevaluate packaging on the basis of claims data. The Panel further recommended that CMS evaluate possible models for threshold levels for packaging radiation therapy guidance and other new technologies.

ASCs are not within the purview of the APC Panel. The APC Panel's advisory role includes specific areas of focus related to the OPPS. We would not expect the APC Panel to make any recommendations related to ASCs and, in fact, there was no APC Panel recommendation related to the impact of packaging for radiation therapy guidance services on the viability of ASCs providing the services as was reported by the commenter. A full discussion of the final OPPS policy related to packaging of radiation therapy guidance services for CY 2009 may be

found in section II.A.4. of this final rule with comment period.

Comment: Many commenters requested that CMS modify the packaging policy to provide separate payment for some services that are not reported by any of the codes within the CPT surgical code range. The commenters stated their belief that as a result of CMS' packaging policy, procedural services that they believe would meet the criteria for performance in ASCs and thereby, would be eligible for payment as covered surgical procedures in ASCs, are being inappropriately excluded from eligibility for payment. More specifically, the commenters disagreed with the ASC packaging policy under which a minor surgical procedure (reported by a code within the CPT surgical code range) is packaged into payment for a radiology service. The commenters argued that the result of the packaging policy is that the surgical procedure is not eligible for separate payment. Because the radiology service is only eligible for separate payment when it is provided integral to a covered surgical procedure, the radiology service is not separately payable when it is the only service being provided.

The commenters expressed particular concern regarding discography services. Packaged into the CPT codes 72285 (Discography, cervical or thoracic, radiological supervision and interpretation) and 72295 (Discography, lumbar, radiological supervision and interpretation) are CPT codes 62290 (Injection procedure for discography, each level; lumbar) and 62291 (Injection procedure for discography, each level; cervical or thoracic). The injection procedures are, by definition, surgical procedures because they are reported by CPT codes in the surgical range. Commenters noted that packaging the surgical code into the radiology service means that the radiology service is included on the ASC list of covered ancillary services and that, therefore, separate payment is only made to an ASC when the radiology service is provided integral to a covered surgical procedure. They believe the radiology service should be separately payable when it is performed alone. The commenters argued that discography services would migrate to HOPDs as a result of this packaging policy. They contended that CMS should provide ASC payment for both the traditional forms of surgery and other invasive procedures appropriate to the outpatient surgical setting.

Response: Packaged surgical services are minor procedures and are usually reported with a more comprehensive procedure that may be nonsurgical and, therefore, excluded from payment under the revised ASC payment system. In the circumstances referred to by the commenters, the minor surgical procedures are performed in support of comprehensive nonsurgical services and payment for the minor surgical procedures is packaged into payment for the nonsurgical services under the OPPS. We do not agree that we should define surgical procedures under the revised ASC payment system to include other types of services, such as radiology services, even though some minor component(s) of the service may be defined as surgical. Instead, we continue to believe that the other types of services, including radiology services, are not appropriate for performance and separate payment in ASCs unless they are integral to covered surgical procedures.

After consideration of the public comments received, we are providing CY 2009 payment for covered ancillary services in accordance with the final policies of the revised ASC payment system as described in the CY 2008 OPPS/ASC final rule with comment period. Covered ancillary services and their final CY 2009 payment indicators are listed in Addendum BB to this final rule with comment period.

G. New Technology Intraocular Lenses

1. Background

In the CY 2007 OPPS/ASC final rule with comment period, 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 (71 FR 67960 and 68176). Specifically, we established the following process:

- We will announce annually in the **Federal Register** 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. Pursuant to Section 141(b)(3) of P.L. 103–432 and our regulations at 42 CFR 416.185(b), the deadline for receipt of public comments will be 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 will—

+ 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, we finalized our proposal to base our determinations on consideration of the following factors set out at 42 CFR 416.195 (71 FR 67960 and 68227):

- 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.
- 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 would be considered 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;

+ 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;

++ 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.hhs.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 would be 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.
- 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 was 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 would 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.hhs.gov/ASCPayment/08_NTIOLs.asp#TopOfPage.*

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.hhs.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. CMS accepts 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, 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 Pre-existing Astigmatism.	STAAR Surgical Elastic Ultraviolet-Absorbing Silicone Posterior Chamber IOL with Toric Optic, models AA4203T, AA4203TF, and AA4203TL.
3	Q1003	February 27, 2006, through February 26, 2011.	Reduced Spherical Aberration.	Advanced Medical Optics (AMO) Tecnis® IOL models Z9000, Z9001, Z9002, ZA9003, AR40xEM and Tecnis® 1-Piece model ZCB00; Alcon Acrysof® IQ Model SN60WF and Acrysert Delivery System model SN60WS; Bausch & Lomb Sofport AO models LI61AOV, and LI61AOV; STAAR Affinity Collamer model CQ2015A, CC4204A, and Elastimide AQ2015A.

b. Request To Establish New NTIOL Class for CY 2009

As discussed below and explained in the guidance document on the CMS Web site, a request for review for a new class of NTIOLs for CY 2009 must have been submitted to CMS by March 14, 2008, the due date published in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We received one request 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

for CY 2009 by the March 14, 2008 due date. A summary of this request follows.

Requestor: Rayner Surgical, Inc.

Manufacturer: Rayner Intraocular Lenses Limited

Lens Model Number: C-Flex IOL, Model Number 570C

Summary of the Request: Rayner Surgical, Inc. (Rayner) submitted a request for CMS to determine that its C-Flex Model 570C intraocular lens meets the criteria for recognition as an NTIOL and to concurrently establish a new class of NTIOLs, with this lens as a member. As part of its request, Rayner submitted descriptive information about the candidate IOL 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 lens, a summary of the IOL's safety and effectiveness, a copy of the FDA's approval notification, and instructions for its use. In addition, Rayner also submitted several peer-reviewed articles in support of its claim that the design features and hydrophilic properties of the candidate lens would reduce silicone oil adhesion and silicone oil-induced opacification. We note that we have previously considered other candidate IOLs for which ASC payment review was requested on the basis of their hydrophilic characteristics or their associated reduction in cellular deposits. We discussed these types of lenses in the December 20, 1999 and May 3, 2000 NTIOL proposed and final rules published in the **Federal Register** (64 FR 71148 through 71149 and 65 FR 25738 through 25740, respectively).

In its CY 2009 request, Rayner asserted that the design features and hydrophilic properties of the candidate lens would reduce silicone oil adhesion and silicone oil-induced opacification problems associated with FDA-approved IOL materials currently marketed in the United States. Rayner stated that silicone oil is widely used as a tamponade in vitreoretinal surgery, and that silicone oil-induced opacification of an IOL, through adherence of the oil to the IOL surface, is a well-known surgical complication. Rayner also stated 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. In the CY 2009 OPPS/ASC proposed rule, we noted that we had begun our review of Rayner's request to recognize its C-Flex IOL as an NTIOL and concurrently establish a new class of NTIOLs. In the CY 2009 OPPS/ASC proposed rule, we solicited comments on this candidate IOL with respect to the established NTIOL criteria as discussed above (73 FR 41536).

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 noted in the CY 2009 OPPS/ASC proposed rule that FDA approval for the candidate lens was granted in May of 2007 and in its request, Rayner 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. The approved label for the Rayner C-Flex stated, ''The hydrophilic nature of the Rayacryl material and the design features of the Rayner C-Flex lens reduce the problems of silicone oil adhesion and silicone oil opacification.'' The FDA label did not otherwise reference specific clinical benefits or lens characteristics with established clinical relevance in comparison with currently available IOLs. Although the labeling reference to reduced ''problems'' could imply clinical relevance and clinical benefits of the lens, the label did not indicate the specific clinical benefits associated with the lens. In the CY 2009 OPPS/ASC proposed rule (73 FR 41536), we noted that we were interested in public comments on the specific clinical benefits and/or lens characteristics with established clinical relevance in comparison with currently available IOLs that may be associated with the silicone adherence and silicone oil-induced opacification reducing characteristics of this candidate lens.

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. Please refer 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 hydrophilic nature of the Rayacryl material and the design features of the C-Flex lens to reduce problems with silicone oil adhesion and silicone oil-induced opacification, 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. In the CY 2009 OPPS/ASC proposed rule (73 FR 41536), we noted that we welcomed public comments that address whether the proposed class-defining characteristic and associated clinical benefits of the candidate Rayner IOL are described by the expired or currently active NTIOL classes.

Third, our NTIOL evaluation criteria also require that an applicant submit evidence that demonstrates use of the IOL results in measurable, clinically meaningful, improved outcomes in comparison with 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 2009, we stated our belief that foldable, spherical, monofocal IOLs made of acrylic, silicone, or polymethylmethacrylate materials represented the currently available lenses against which the candidate NTIOL to establish a new class should be compared. The Rayner request asserted that the hydrophilic material of the candidate lens with respect to silicone oil adhesion made the lens a novel IOL in the U.S. market. In the CY 2009 OPPS/ASC proposed rule (73 FR 41536), we sought public comment on our view of ''currently available lenses'' for the purposes of this CY 2009 review.

We reviewed the four peer-reviewed articles submitted by Rayner with the request, specifically three bench studies of silicone oil coverage of various IOL materials and a single series of three clinical case histories where silicone oil adhesion was documented. The literature did not clearly provide information regarding the clinical benefit to patients who received the candidate lens in conjunction with cataract removal surgery compared to patients receiving currently available IOLs. As stated in the Rayner request, the potential benefits of the candidate lens would apply only to individuals undergoing vitreoretinal surgery, in which silicone oil was used as a tamponade at some time after insertion of the intraocular lens. The size and composition of this population that could potentially benefit was unclear, and it was also unclear how often and what other alternative tamponade materials may be employed in the U.S relative to silicone oil. In the CY 2009 OPPS/ASC proposed rule (73 FR 41536), we welcomed public comments and relevant data specifically addressing whether use of the Rayner C-Flex IOL resulted in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs.

In accordance with our established NTIOL review process, we sought public comments on all of the review criteria for establishing a new NTIOL class with the characteristic of reduced silicone oil-induced opacification based on the request for the Rayner C-Flex IOL Model 570C lens. All comments on this request must have been received by August 18, 2008. We stated that the announcement of CMS' determination regarding this request would appear in this CY 2009 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 would be effective 30 days following the date that this final rule with comment period is published in the **Federal Register**.

We thank the public for their comments concerning our review of the request from Rayner Surgical, Inc. to establish a new class of NTIOLs based on the characteristics of its C-Flex IOL Model 570C. Some of the comments we received raised additional questions about the proven effectiveness of the Rayner C-Flex lens, especially when compared to other currently available lenses. These public comments and our responses to them are summarized below.

Comment: One commenter expressed general support for CMS' integration of the new NTIOL notice and comment process into the annual OPPS/ASC rulemaking cycle. The commenter cautioned that the process should be monitored to ensure that the consideration of these new technologies is not impeded or slowed by the rulemaking process. Additionally, the commenter requested that for consistency the NTIOL comment period should coincide with the comment period for the remainder of the issues included in the annual OPPS/ASC proposed rule.

Response: We thank the commenter for the support of our integration of the new NTIOL notice and comment process into the annual OPPS/ASC rulemaking cycle. However, in response to the request that the comment period regarding requests to establish new classes of NTIOLs should coincide with the comment period for all other issues included in the annual OPPS/ASC proposed rule, we note that section 141(b)(3) of the Social Security Act Amendments of 1994, Public Law 103–432, clearly requires us to provide a 30-day comment period on lenses that are the subject of requests for recognition as belonging to a new class of NTIOLs. Therefore, we will continue to provide a 30-day comment period on lenses that are the subject of requests for recognition as members of a new class of NTIOLs.

Comment: One commenter responded to CMS' view of the present definition of currently available lenses. The commenter believed that the definition of ''currently available IOLs'' should take into account the most recent preceding level of technological advancement and corresponding patient benefit that has been or is rapidly becoming accepted by the ophthalmologic medical community. The commenter suggested that in order to identify the latest technological advancement, CMS should consider market shares and/or growth rates of various classes of currently available IOLs. The commenter further stated that IOLs that reduce spherical aberration have become the technology of choice for most cataract surgeons because of the greater quality of vision they provide. The commenter concluded that CMS should be reluctant to establish a new NTIOL class for a future candidate IOL that does not reduce spherical aberration.

Response: We will consider and evaluate this particular concept of ''currently available lenses'' for its applicability to our future reviews of NTIOL applications. While we would expect that use of IOLs seeking NTIOL recognition would result in improved clinical outcomes when compared to currently available lenses, which includes lenses with the characteristic of reducing spherical aberration, we do not require that lenses seeking NTIOL recognition also share the same characteristics as other lenses that are in currently active NTIOL classes. As discussed in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68178), we continue to believe that flexibility is critical when identifying what the public considers ''currently available lenses,'' in order to allow for consideration of technological advances in lenses over time.

Comment: One commenter questioned how CMS could expect a comparison reference to be included in an FDA-approved label, as the FDA's legal authority is only to determine if a product is safe and effective. Furthermore, the commenter stated that to expect a device label to contain language remarking about the device's performance in relation to other similar devices makes meeting the NTIOL criteria impossible. The commenter did not believe that the labels of the IOLs that have received NTIOL status contained such language.

Response: In response to the comment regarding the FDA's legal authority to make comparative decisions, we note that it was not our intent to suggest that the FDA makes comparative decisions, but rather that the FDA-approved label, submitted by an applicant, may include benchmark studies that have compared the performance of the applicant's lens against the performance of other lenses. We have reviewed requests for NTIOL class recognition where the FDA-approved label has included such comparative bench studies, and we do use this information in our review process.

Comment: One commenter claimed that the C-Flex lens application to establish a new NTIOL category meets the specific NTIOL review criteria and that the applicant lens is not described

by current or prior classes of NTIOLs. This commenter asserted that the C-Flex IOL offers patients who go on to require vitreoretinal surgery clinically meaningful improvements, such as a decreased rate of subsequent therapeutic interventions and a decreased incidence of subsequent IOL exchange. The commenter also argued that the C-Flex IOL provides beneficiaries who go on to require vitreoretinal surgery with more stable postoperative vision because patients who suffer from silicone oil adhesion to their implanted IOL lose visual acuity and either must live with impaired vision or undergo another surgical procedure to remove the damaged lens and have a new IOL inserted. The commenter pointed out that silicone oil used as a tamponade agent during vitreoretinal surgery may need to be left in the vitreal space for many months following surgery, resulting in silicone adherence to a vast majority of the currently available IOLs identified by CMS. The commenter concluded that silicone oil adherence to the IOL creates both immediate and long-term problems for patients, as well as the retinal surgeon. Such problems include decreased visualization of the operative area by the surgeon and reoperation on the eye, which exposes the patient to significant surgical risks.

The commenter claimed that 15,000 to 30,000 of the approximately 1.5 million cataract surgery patients per year in the United States go on to require vitreoretinal surgery, and not an insignificant number of these individuals face surgical risks associated with silicone oil adherence. The commenter stated that the benefit from the C-Flex IOL is not dependent on the number of patients who might be impacted but rather the clinical outcomes at issue.

Another commenter explained that problems of silicone oil adhesion and silicone oil opacification have been primarily attributed to silicone IOLs, and some experts advise that silicone IOLs not be implanted in patients at risk for vitreoretinal surgery. This commenter asserted that published peer-reviewed articles in the medical literature conclude that either a hydrophobic or a hydrophilic acrylic IOL is preferable (for greater visibility) to a silicone IOL in patients at risk for future vitreoretinal surgery. The commenter further stated that silicone IOLs have been replaced in the United States to a large extent by hydrophobic acrylic IOLs based on surgeon preferences and common clinical scenarios. In addition, the commenter explained that many studies have documented postoperative optic opacification due to calcification in hydrophilic acrylic IOLs and that postoperative opacification of these lenses is of concern, given that the supposed additional benefit of the hydrophilic C-Flex IOL is superior clarity in eyes exposed to silicone oil. The commenter further claimed that recent publications identify ''secondary calcification'' with hydrophilic acrylic IOLs as a phenomenon seen in eyes with complicated pathology (such as vitreoretinal surgery). The commenter questioned the bench studies cited in the C-Flex IOL FDA label, stating that there is no evidence that relatively small differences in silicone oil coverage (as measured in the bench tests) translates into any clinically meaningful benefit.

Two commenters responded to the question as to whether surgeons have alternatives to silicone oil. One commenter stated that retinal surgeons could opt to use gas or air for their tamponade effect, but that use of these substitutes during vitreoretinal surgery did not avoid visual problems. This commenter believed that while there are some options to address certain aspects of the silicone oil adherence problem, none of these options completely resolves the problem and therefore the C-Flex lens provides a clinical benefit as compared to each of these alternatives. The other commenter asserted that choices of retinal tamponades include silicone oil, gases, and perfluorocarbon liquids, all of which are indicated for use in treating retinal detachments. This commenter further stated that the choice of tamponade is based on each patient's presentation and specific pathology, and that the alternatives are generally not interchangeable. The commenter also explained that silicone oil is not used in every retinal detachment procedure and that in some cases of retinal detachment, surgeons use a scleral buckle procedure that does not utilize a retinal tamponade. Another commenter did not offer alternative materials that could be used as a tamponade but stated that published peer-reviewed articles in the medical literature conclude that either a hydrophobic or a hydrophilic acrylic IOL is preferable (for greater visibility) to a silicone IOL in patients at risk for retinal surgery.

Response: As we have stated in prior rulemaking, we fully expect that to be recognized as an NTIOL and to subsequently establish a new NTIOL class, the insertion of the candidate IOL would result in significantly improved clinical outcomes compared to currently available IOLs, and 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 were identified for each class. We agree that the applicant lens is not described by current or prior classes of NTIOLs. We also agree that clinical outcomes rather than number of patients that may be impacted should be the focus of our decision. However, we note that with respect to the applicant lens, there are no published comparable clinical data available or presented by the applicant which demonstrate that use of the C-Flex IOL results in measurable, clinically meaningful, improved outcomes in comparison with use of currently available IOLs. The applicant submitted studies that evaluated the adhesion of silicone oil to various IOL materials and these studies conclude, to varying degrees, that lenses made of hydrophilic material exhibit lower silicone oil adhesion than lenses made of hydrophobic materials. However, the clinical relevance of these bench studies submitted by the applicant has not been established. We agree with the comment that several studies have documented postoperative opacification of hydrophilic lenses. In our review of the studies submitted by the applicant and other available data and studies, we encountered information, similar to the peer-reviewed journal articles submitted by one commenter that suggested that hydrophilic lenses may be susceptible to other forms of opacification. If this were the case, any potential visual benefit from reduced silicone oil opacification might not be realized.

After consideration of the public comments received, we conclude that the Rayner C-Flex IOL does not demonstrate substantial clinical benefit in comparison with currently available IOLs. Therefore, we are disapproving Rayner's request to recognize its C-Flex (model 570) IOL as an NTIOL and, therefore, we are not establishing a new class of NTIOL for payment as a result of this CY 2009 review cycle.

4. 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 will be made and how an NTIOL will be paid after expiration of the payment adjustment, and made minor editorial changes to § 416.200(d). For CY 2008, we did not revise the current payment adjustment amount, and we did not propose to revise the payment adjustment amount for CY 2009 in light of our very short experience with the

revised ASC payment system, implemented initially on January 1, 2008. Therefore, the final ASC payment adjustment amount for NTIOLs in CY 2009 is $50.

5. ASC Payment for Insertion of IOLs

In accordance with the final policies of the revised ASC payment system, for CY 2009, 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 2009 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 proposed CY 2009 ASC payment rates for IOL insertion procedures were included in Table 44 of the CY 2009 OPPS/ASC proposed rule (73 FR 41537).

We did not receive any public comments concerning the proposed CY 2009 payment rates for the insertion of IOL procedures. Therefore, we are finalizing the payment rates for the insertion of IOL procedures, calculated according to the standard methodology of the revised ASC payment system, as shown in Table 50 below for CY 2009.

TABLE 50—INSERTION OF IOL PROCEDURES AND THEIR CY 2009 ASC PAYMENT RATES

CY 2009 HCPCS code	CY 2009 Long descriptor	Final CY 2009 ASC payment
66983	Intracapsular cataract extraction with insertion of intraocular lens prosthesis (one stage procedure)	$964.70
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification).	964.70
66985	Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract removal	893.03
66986	Exchange of intraocular lens	893.03

6. Announcement of CY 2009 Deadline for Submitting Requests for CMS Review of Appropriateness of ASC Payment for Insertion of an NTIOL Following Cataract Surgery

In accordance with § 416.185(a) of our regulations as revised by the CY 2007 OPPS/ASC final rule with comment period, CMS announces that in order to be considered for payment effective January 1, 2010, requests for review of applications for a new class of new technology IOLs must be received at CMS by 5 p.m. EST, on March 2, 2009. Send requests to ASC/NTIOL, Division of Outpatient Care, Mailstop C4–05–17, Centers for Medicare and Medicaid, 7500 Security Boulevard, Baltimore, MD 21244–1850.

To be considered, requests for NTIOL reviews must include the information on the CMS Web site at: *http://www.cms.hhs.gov/ASCPayment/08_NTIOLs.asp#TopOfPage*.

H. ASC Payment and Comment Indicators

1. Background

In addition to the payment indicators that we introduced in the August 2, 2007 final rule for the revised ASC payment system, 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, including: Their ASC payment status prior to CY 2008; their designation as device-intensive or office-based and the corresponding ASC payment methodology; and their classification as separately payable 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 this final rule 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 final rule to indicate new HCPCS codes for which the interim payment indicator assigned is subject to comment on this final rule with comment period.

The ''CH'' comment indicator was used in Addenda AA and BB to the CY 2009 OPPS/ASC proposed rule to indicate that: A new payment indicator (in comparison with the indicator for the CY 2008 ASC April quarterly update) was proposed for assignment to an active HCPCS code for the next calendar year; an active HCPCS code was proposed for addition to the list of procedures or services payable in ASCs; or an active HCPCS code was proposed for deletion at the end of the current calendar year. The ''CH'' comment indicators that are published in this 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, respectively, to this final rule with comment period.

2. ASC Payment and Comment Indicators

In the CY 2009 OPPS/ASC proposed rule, we proposed to revise the definition of one ASC payment indicator for CY 2009 (73 FR 41537). We proposed that the definition of payment indicator ''F4'' would be changed from ''Corneal tissue acquisition; paid at reasonable cost'' to ''Corneal tissue acquisition, hepatitis B vaccine; paid at reasonable cost'' for CY 2009. The revised definition was displayed in Addendum DD1 to the CY 2009 OPPS/ASC proposed rule.

We did not receive any public comments that addressed our proposal related to implementation of a revised definition for payment indicator ''F4''. We are finalizing our proposal, without modification, to adopt the payment indicators as defined in Addendum DD1 to this final rule with comment period.

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

1. Background

In the August 2, 2007 final rule, we made final our proposal to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and relative payment weights (72 FR 42493). 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 existing (CY 2007) ASC payment system. That is, application of the ASC conversion factor was designed to result in aggregate expenditures under the revised ASC payment system in CY 2008 equal to aggregate expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on payments in CY 2007 as required under section 1833(i)(2)(E) of the Act (72 FR 42521 through 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 for most services as the ASC relative payment weights and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures and covered ancillary radiology services, the final policy is to set the relative payment weights so that the national unadjusted ASC payment rate does not exceed the MPFS unadjusted nonfacility PE RVU amount. Further, as discussed in section XV. of the CY 2009 OPPS/ASC proposed rule, in addition to the standard payment methodology, we also adopted several other alternative payment methods for specific types of services (for example, device-intensive procedures) (73 FR 41523 through 41539).

Beginning in CY 2008, Medicare accounts 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 index 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 index, which is updated yearly and is used by many other Medicare payment systems, appropriately accounts for geographic variances in labor costs for ASCs.

As discussed in the August 2, 2007 revised ASC payment system final rule (72 FR 42518), 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 index to the labor-related portion, which is 50 percent of the ASC payment amount.

In the CY 2009 OPPS/ASC proposed rule, we noted that as part of our review of the hospital wage index, in accordance with section 106(b)(2) of the MIEA–TRHCA, CMS has initiated a research contract that will include analysis and recommendations on alternatives to the current method for computing the IPPS wage index for FY 2009. We received an interim report on this analysis in August 2008 that is available on the Web site at *http://www.acumenllc.com/reports/cms/RevisedImpactAnalysisfor2009FinalRule.pdf.* We anticipate a final report in the winter of 2009. While the majority of that final report will address the impact of changes on the IPPS wage index, report recommendations should provide some information about how proposals to refine the IPPS wage index, including modification or elimination of the reclassification process and adoption of Bureau of Labor Statistics data, may result in a more appropriate wage index for non-IPPS providers (73 FR 48564).

2. Policy Regarding Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2009 and Future Years

We update the ASC relative payment weights in the revised ASC payment system each year using the national OPPS relative payment weights (and MPFS nonfacility 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, in the CY 2009 OPPS/ASC proposed rule (73 FR 41538), we proposed to scale the CY 2009 relative payment weights for ASCs according to the following method. Holding ASC utilization and the mix of services constant from CY 2007, for CY 2009, we would compare the total payment weight using the CY 2008 ASC relative payment weights under the 75/25 blend (of the CY 2007 payment rate and the revised ASC payment rate) with the total payment weight using the CY 2009 ASC relative payment weights under the 50/50 blend (of the CY 2007 ASC payment rate and the revised ASC payment rate) to take into account the changes in the OPPS relative payment weights between CY 2008 and CY 2009. We would use the ratio of CY 2008 to CY 2009 total payment weight (the weight scaler) to scale the ASC relative payment weights for CY 2009. The proposed CY 2009 ASC scaler was 0.9753 and scaling of ASC relative payment weights would apply to covered surgical procedures and covered ancillary radiology services whose 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 under the OPPS 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.

The proposed weight scaler used to model ASC fully implemented rates in order to reflect our estimate of rates if there was no transition for CY 2009 was equal to 0.9412. This scaler was applied to all payment weights subject to scaling, in order to estimate the fully implemented payment rates for CY 2009 without the transition, for purposes of the ASC impact analysis discussed in section XXI.C. of the CY 2009 OPPS/ASC proposed rule (73 FR 41562).

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. When we developed the CY 2009 OPPS/ASC proposed rule, we had available 95 percent of CY 2007 ASC claims data. These claims did not include new covered surgical procedures and covered ancillary services under the revised ASC payment system that were first payable in ASCs in CY 2008 and only contained data for ASC services billed in CY 2007 that were eligible to receive payment under the previous ASC payment system. We did not have sufficiently robust CY 2008 ASC claims data upon which to base the CY 2009 ASC payment system update. Therefore, for CY 2009 budget neutrality adjustments, we assumed that there would be no significant change in the weight scaler or wage adjustment attributable to new covered surgical and covered ancillary services.

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 2007 ASC claims by provider and by HCPCS code. We created a unique supplier identifier solely for the purpose of identifying unique providers within the CY 2007 claims data. We used the provider zip code reported on the claim to associate state, county, and CBSA with each ASC. This file, available to the public as a supporting data file for the CY 2009 OPPS/ASC proposed rule, is posted on the CMS Web site at: *http://www.cms.hhs.gov/ASCPayment/01_Overview.asp#TopOfPage*.

Comment: Many commenters opposed scaling the ASC relative payment weights, expressing similar opinions to those public comments that were summarized when CMS finalized the CY 2009 scaling policy in the August 2, 2007 revised ASC payment system final rule. These commenters expressed many concerns, including that scaling is inappropriate and will continue to erode the relationship between the ASC payment system and the OPPS.

Numerous commenters asserted that CMS is not required to scale the ASC relative weights and that it should use its administrative authority and not apply the ''secondary'' scaler to ASC relative weights in CY 2009. They noted that CMS established at § 416.171(e)(2) a process by which it *may* (emphasis added) make annual adjustment to the relative payment weights, *as needed* (emphasis added).

Most commenters believed that the scaling would result in decreased ASC expenditures in CY 2009. On the other hand, some commenters contended that suspending application of the scaler would result in an aggregate increase in spending in the ASC setting in CY 2009, although the commenters believed this increase in spending would be appropriate. In addition, many of the commenters indicated that the fact that the weights are already scaled to ensure budget neutrality under the OPPS means that they should not be scaled (''secondary rescaling'') to ensure budget neutrality under the ASC system.

Many commenters expressed concern that other payment adjustments are already depressing the ASC payments for many procedures, including the freeze on the ASC payment update and the transition policy and that scaling further reduces rates to inappropriately low levels. Further, the commenters stated that scaling has a disproportionate impact on some types of covered surgical procedures and that the differences in the mix of services between the OPPS (where lower cost primary care and diagnostic services are included in relative weight scaling) and ASCs, as well as the ''secondary rescaling'' of the relative weights for ASC procedures effectively resulted in penalizing ASCs for performing only surgical procedures.

The commenters also expressed their belief that the lack of ASC volume data for 40 percent of the covered surgical procedures raises substantial methodological issues. They stated that perhaps CMS should put off scaling the ASC weights until there are ASC data that reflect actual experience under the revised payment system.

Finally, the commenters asserted that the scaling would lead to access to care problems for Medicare beneficiaries.

Response: Many of these comments are similar to public comments on the proposal for the revised ASC payment system that we responded to in the August 2, 2007 revised ASC payment system final rule. For example, we noted in that August 2, 2007 final rule that commenters ''were concerned that annual rescaling would cause divergence of the relative weights between the OPPS and the revised ASC payment system for individual procedures.'' (72 FR 42532) While we continue to appreciate the commenters' concerns, we refer the commenters to the discussion in the August 2, 2007 revised ASC payment system final rule for our detailed response in promulgating the final CY 2009 scaling policy (72 FR 42531 through 42533). Below, we address new issues raised by the commenters and provide a general summary of some of the relevant responses from the August 2, 2007 final rule.

With respect to the use of ''as needed'' in the text of § 416.171(e)(2), we note that this section says ''* * * CMS adjusts the ASC relative payment weights under 416.167(b)(2) as needed so that any updates and adjustments made under 419.50(a) of this subchapter are budget neutral as estimated by CMS.'' This does not mean that CMS will determine whether or not to adjust for budget neutrality. Rather, it means that CMS adjusts the relative payment weights as needed to ensure budget neutrality. If we were not to scale the ASC relative payment weights, we estimate that the CY 2009 updates and adjustments would not be budget neutral. This result would be counter to the rationale for the scaling policy described in the August 2, 2007 revised ASC payment system final rule (72 FR 42532).

We agree with the commenters who indicated that suspending application of the scaler would result in an aggregate increase in spending in the ASC setting in CY 2009. However, we disagree with the commenters that this increase in spending would be appropriate because, as we discussed in the August 2, 2007 revised ASC payment system final rule, we continue to believe that it is inappropriate for ASC expenditures to increase or decrease as a result of changes in the relative payment weights or the wage index. Changes in aggregate ASC expenditures related to payment rates should be determined by the update to the ASC conversion factor. Specifically, we stated that, ''Rescaling of relative weights or the application of a budget neutrality adjustment is a common feature of Medicare payment systems, designed to ensure that estimated aggregate payments under a payment system for an upcoming year would be neither greater nor less than the aggregate payments that would be made in the prior year, taking into

consideration any changes or recalibrations for the upcoming year. * * * We continue to believe that this principle should apply as well in the revised ASC payment system.'' (72 FR 42532)

The ASC weight scaling methodology is entirely consistent with the OPPS methodology for scaling the relative payment weights. Establishing budget neutrality under the OPPS does not result in budget neutrality under the revised ASC payment system. Scaling the ASC relative payment weights is not a ''secondary rescaling'' of the OPPS relative payment weights; there are two separate processes for the two separate payment systems.

In order to maintain budget neutrality of the ASC payment system, CMS needs to adjust for the effects of wage index changes and relative weight changes even though there are other factors affecting ASC payment rates. However, the use of a uniform scaling factor does not alter the relativity of the OPPS payment weights as used in the ASC payment system. Differences in the relativity between the ASC relative payment weights and the OPPS relative payment weights are not driven by the application of the uniform scaling factor. To the extent that commenters objected to the effects of other payment policies of the revised ASC payment system, the uniform scaling factor is not the driver of the effects of those payment policies. Our ASC weight scaling methodology is entirely consistent with the OPPS weight scaling methodology.

Regarding commenters' concern that scaling has a disproportionate effect on some types of covered surgical procedures, we note that, as explained in the August 2, 2007 revised ASC payment system final rule (72 FR 42542), a major effect of the revised ASC payment system is redistribution of payments across all ASC procedures. Historically, the highest volume ASC procedures had payment rates that were close to the payments in HOPDs and, as such, accounted for most of the total Medicare payments to ASCs. As a result, payments for many of those high volume services are the most adversely affected under the revised payment system as the relative weights across all ASC procedures become more closely aligned with those under the OPPS.

With respect to the use of CY 2007 ASC claims data, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. For CY 2009, the most recent full year of data available is CY 2007 ASC claims data. On the other hand, we recognize that partial 2008 ASC claims data do contain at least some utilization for the new covered surgical procedures and covered ancillary services under the revised ASC payment system. We considered trying to use CY 2008 ASC data in developing the CY 2009 OPPS/ASC proposed rule and, on balance, concluded that given the newness of the revised ASC payment system, we continue to believe that it is more appropriate to use full CY 2007 data in the development of the CY 2009 ASC payment rates, rather than incomplete CY 2008 claims data. We expect to use the full, complete CY 2008 claims data in the development of the CY 2010 ASC payment rates.

We do not believe that the application of the scaler will lead to beneficiary access problems. We believe that the fully implemented relative weights will be representative of relative costs across all ASC services and that payments will support the continued provision of high quality surgical procedures to Medicare beneficiaries. We also expect that over time ASCs will provide an increased breadth of services. However, appropriate beneficiary access to services in appropriate care settings is always an important concern and we will continue to monitor access under the revised ASC payment system.

Comment: Commenters also criticized the relative weight scaler and transitional payment methodologies for resulting in relatively larger ASC payment decreases for the highest volume ASC procedures than for other ASC procedures. They estimated that payment decreases for the seven highest volume ASC procedures are responsible for financing 50 percent of the payment increases for other procedures that have payment rates that have historically lagged far below the OPPS rates. They asserted that this represented a disproportionate and inappropriate effect on the highest volume ASC services. They argued that it was not fair for CMS to attempt to balance budget neutrality for the revised ASC payment system on reduced payment for only a few ASC services.

Response: The GAO found that OPPS relative payment weights were reflective of the relative costs among the same procedures in ASCs. As we explained in the August 2, 2007 revised ASC payment system final rule (72 FR 42542), a major effect of the use of the OPPS relativity in the revised ASC payment system is a redistribution of payments across all ASC procedures. We noted that many procedures for which the relativity under the OPPS was higher than the relativity under the old ASC payment system would experience significant payment increases as payments under the revised ASC payment system would be made based on the relativity found under the OPPS. Many of those procedures were historically lower volume ASC services. Conversely, however, procedures for which the relativity under the old ASC payment system was higher than the relativity under the OPPS, like many of the high volume ASC procedures mentioned by the commenters, would see payment decreases under the revised ASC payment system. As described in the August 2, 2007 revised ASC payment system final rule, we are transitioning these payment changes over 4 years to allow time for ASCs to adjust to the new payment structure (72 FR 42521).

As stated earlier, the use of a uniform scaling factor does not alter the relativity of the OPPS payment weights as used in the ASC payment system. Differences in the relativity between the ASC relative payment weights and the OPPS relative payment weights are not driven by application of the uniform scaling factor. For a further discussion of the transition policy and the effect of scaling on the relativity of the ASC payment weights, we refer readers to the August 2, 2007 revised ASC payment system final rule (72 FR 42519 through 42521 and 42531 through 42533).

Comment: A number of commenters requested that CMS recalculate the payment rate for CPT code 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), the highest volume ASC procedure. Some commenters stated that they could not calculate the payment amount that CMS published as the national unadjusted rate in the CY 2009 OPPS/ASC proposed rule. Other commenters noted that the ASC payment rate for CPT code 66984 should have increased slightly for CY 2009 because the OPPS rate increased. They argued that if the payment system was functioning as it was described in the August 2, 2007 revised ASC payment system final rule, the CY 2009 payment for CPT code 66984 should have increased by $1.13, but instead, due to rescaling, the proposed CY 2009 ASC payment for the procedure decreased.

Other commenters understood the method for calculation and indicated their belief that CMS should not apply the scaler to the CY 2007-based portion of the CY 2009 payment rate for this or other HCPCS codes subject to the transition. They noted that, in the August 2, 2007 revised ASC payment system final rule, the final policy called

for a CY 2009 transitional blend of 50 percent of the CY 2007 payment rate for a covered surgical procedure on the CY 2007 ASC list of covered surgical procedures and 50 percent of the CY 2009 payment rate for the procedure calculated under the ASC standard methodology. Thus, these commenters believed that CMS' scaling of the entire blended CY 2009 ASC payment weight was not appropriate because this methodology decreased the CY 2007 payment amount contributing to the procedure's lower CY 2009 proposed transitional ASC payment rate.

Response: To calculate the transitional rate for CY 2009 for CPT code 66984, the CY 2007 payment rate portion of the blended rate must be adjusted by the relative weight scaling factor. The commmenters who could not calculate a CY 2009 payment rate for CPT code 66984 that matched the rate included in the CY 2009 OPPS/ASC proposed rule likely did not scale the ASC transitional payment weight associated with the blended CY 2009 payment rate for CPT code 66984.

The issue of the inclusion of the transition in the calculation of the CY 2009 scaling factor was clearly addressed in the August 2, 2007 revised ASC payment system final rule where we specifically indicated that ''holding ASC utilization and the mix of services constant, for CY 2009, we will compare the total weight using the CY 2008 ASC relative payment weights under the 75/25 blend (of the CY 2007 payment rate and the revised payment rate) with the total weight using CY 2009 relative payment weights under the 50/50 blend (of the CY 2007 payment rate and the revised payment rate), taking into account the changes in the OPPS relative payment weights between CY 2008 and CY 2009. We will use the ratio of CY 2008 to CY 2009 total weight to scale the ASC relative payment weights for CY 2009.'' (72 FR 42533)

In addition to explicitly stating in the August 2, 2007 revised ASC payment system final rule how we would incorporate the transition into the CY 2009 scaling calculation, we indicated in the methodology describing our calculation of the final estimated CY 2008 budget neutrality adjustment that ''the budget neutrality calculation is calibrated to take into account the CY 2008 transitional payment rates for procedures on the CY 2007 list of covered surgical procedures.'' (72 FR 42531) In other words, the CY 2008 budget neutrality adjustment took into account the transition and was not based on the fully implemented system.

It would be inconsistent with the final policies established in the August 2, 2007 revised ASC payment system final rule and the calculation of the CY 2008 ASC conversion factor for us to calculate the CY 2009 budget neutrality adjustment without taking the transition into account and base it only on the fully implemented system, as was suggested by some commenters.

After consideration of the public comments received, we are finalizing, without modification, our CY 2009 ASC relative payment weight scaling methodology. The final CY 2009 ASC payment weight scaler is 0.9751.

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 for the upcoming year, to the conversion factor. For the CY 2009 ASC payment system, we proposed to calculate and apply the pre-floor and pre-reclassified hospital wage index that is 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 2009, we calculated this proposed adjustment for the revised ASC payment system by using the most recent CY 2007 claims data available and estimating the difference in total payment that would be created by introducing the CY 2009 pre-floor and pre-reclassified hospital wage index. Specifically, holding CY 2007 ASC utilization and service-mix and CY 2009 national payment rates after application of the weight scaler constant, we calculated the total adjusted payment using the CY 2008 pre-floor and pre-reclassified hospital wage index and a total adjusted payment using the proposed CY 2009 pre-floor and pre-reclassified hospital wage index. We used the 50-percent labor-related share that we finalized for the revised ASC payment system in CY 2008 for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2008 pre-floor and pre-reclassified hospital wage index to the total adjusted payment calculated with the proposed CY 2009 pre-floor and pre-reclassified hospital wage index and applied the proposed rule resulting ratio of 0.9996 (the ASC wage index budget neutrality adjustment) to the CY 2008 ASC conversion factor to calculate the proposed CY 2009 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 after CY 2009, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for All Urban Consumer (CPI–U) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. Therefore, as discussed in the August 2, 2007 revised ASC payment system final rule, we adopted a final policy to update the ASC conversion factor using the CPI–U in order to adjust ASC payment rates for inflation (72 FR 42518 through 42519). We will implement the annual updates through an adjustment to the conversion factor under the revised ASC payment system beginning in CY 2010 when the statutory requirement for a zero update no longer applies. Therefore, for CY 2009, we only proposed to update the ASC conversion factor with the budget neutrality adjustment due to the revised CY 2009 pre-floor and pre-reclassified hospital wage index, resulting in a proposed CY 2009 ASC conversion factor of $41.384, which was the product of $41.401 multiplied by 0.9996.

Comment: One commenter questioned CMS' determination of the CY 2008 wage index as finalized in the CY 2008 OPPS/ASC final rule with comment period. The commenter inquired as to how local wage index assignments were determined and, more specifically, how a facility was determined to be rural.

Response: In June 2003, the Office of Management and Budget (OMB) announced revised standards for designating the geographic statistical areas that CMS uses to define labor market areas for purposes of assigning the wage index. Specifically, the OMB announced that labor market areas would no longer be defined as Metropolitan Statistical areas (MSAs), but instead as Core Based Statistical Areas (CBSA). OMB further divided these CBSAs into metropolitan statistical areas and micropolitan statistical areas, which, in accordance with established policy, CMS treats as urban and rural, respectively (69 FR 49026 through 49034). Areas not located in any CBSA also are considered rural.

Since June 2003, CMS has transitioned from MSA designations to the CBSA designations. As a result of this change, some facilities that were previously located in urban areas might now be located in areas deemed as rural under the revised standards. The same would also apply to facilities that were previously located in rural areas and are now located in urban areas. In the August 2, 2007 revised ASC payment system final rule (72 FR 42517 through 42518), we finalized the policy of assigning the wage index to ASCs based on their CBSA designation, instead of MSAs, under the revised ASC payment

system. Therefore, the wage index that is assigned to an ASC is based on the CBSA in which the facility is physically located. The OMB periodically updates the CBSA designations using census data, and we reflect those updates in assignment of the wage index each year. A crosswalk that maps the prior MSA labor market area designations to the revised CBSA designations is available on the CMS Web site and can be accessed at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN.*

Comment: Many commenters requested that CMS adopt the same wage index for ASCs as CMS uses to adjust payment under the OPPS. Commenters contended that because ASCs offer services that are very similar to those provided in HOPDs and, therefore, the facilities are competing for the same type of staff, the same wage adjustments should apply.

Response: We believe that the pre-floor, pre-reclassification hospital wage index that we use for our other nonacute care hospital payment systems is appropriate for the ASC payment system. However, as noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41538), in accordance with section 106(b)(1) of the MIEA–TRCHA, CMS has initiated a research contract that will evaluate the application of the hospital wage index in noninpatient settings. We may reconsider our wage policies in light of the findings from that study when they become available.

Comment: Many commenters contended that payment for services provided in ASCs should be made based on a fixed percentage of the OPPS rates. Several commenters indicated that two bills have been introduced in Congress to set and keep ASC payment rates at 75 percent of HOPD payments. These commenters expressed support for the legislation and their belief that 75 percent would balance Medicare's need for savings with an ASC payment rate that could promote growth and development of ASCs and ultimately lead to greater long-term savings for Medicare as procedures shift from more costly HOPDs. These commenters reiterated their belief that CMS' method for establishing budget neutrality for the revised ASC payment system was flawed and has resulted in payments that are too low to sustain ASC services for Medicare beneficiaries.

Commenters were also concerned that updating the conversion factor for the revised ASC payment system using the CPI–U instead of the hospital market basket used to update the OPPS would cause divergence in the relationship between payment to HOPDs and ASCs over time that would not be based on growing differences between the costs of providing procedures in those two different settings. The commenters asserted that hospitals and ASCs experience similar inflationary pressures. Therefore, they recommended that CMS use the hospital market basket as the update for inflation under the revised ASC payment system because that update would more appropriately reflect inflation in the costs of providing surgical services. In addition, the commenters believed that the same update under the two payment systems would allow for a consistent relationship between their payments for the same surgical procedures.

Response: Many of these comments are similar to comments we responded to in the August 2, 2007 revised ASC payment system final rule. For example, we noted in that final rule that ''[s]everal commenters specifically recommended that CMS adopt 75 percent as the multiplier to the OPPS conversion factor, so that payment rates under the revised ASC payment system would be 75 percent of the OPPS rates. They cited legislation that was introduced in the U.S. Senate in 2003 in which payments to ASCs were to have been provided at 75 percent of the OPPS rates.'' (72 FR 42526) We also stated in the final rule (72 FR 42518) that commenters ''expressed concern that the use of two different factors to update payments for ASCs and HOPDs would further increase the discrepancies between payments in the two settings.''

While we continue to appreciate the commenters' concerns, to the extent that the commenters are addressing the methodology for calculating the CY 2008 conversion factor, we refer them to the discussion of the methodology in the August 2, 2007 revised ASC payment system final rule (72 FR 42521 through 42531). To the extent commenters are concerned about the CY 2009 update to the conversion factor, ASCs are not eligible for an update in CY 2009, as required by statute. Finally, to the extent commenters are concerned about updates to the ASC conversion factor for years after CY 2009, we note that we did not propose to change the conversion factor update methodology and we refer readers to the discussion in the August 2, 2007 revised ASC payment system final rule on this issue (72 FR 42518 through 42519).

After consideration of the public comments received, we are finalizing our proposed methodology for determining the final CY 2009 ASC conversion factor. Using more complete CY 2007 data for this final rule with comment period, we calculated a wage index budget neutrality adjustment of 0.9998 for this final rule with comment period. The final ASC conversion factor of $41.393 is the product of the CY 2008 conversion factor of $41.401 multiplied by 0.9998.

3. Display of ASC Payment Rates

Addenda AA and BB to this CY 2009 OPPS/ASC final rule with comment period display the updated ASC payment rates for CY 2009 for covered surgical procedures and covered ancillary services, respectively. These addenda contain several types of information related to the CY 2009 payment rates. Specifically, in Addendum AA, the column titled ''Subject to Multiple Procedure Discounting'' indicates whether a 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 change in payment policy for the item or service from CY 2008 to CY 2009, including identifying new or discontinued HCPCS codes, designating items or services new for payment under the ASC payment system, and identifying items or services with changes in the ASC payment indicator for CY 2009.

The column titled ''CY 2009 Second Year Transition Payment Weight'' is the relative transition payment weight for the service. CY 2009 is the second year of a 4-year transition to ASC payment rates calculated according to the standard methodology of the revised ASC payment system. The CY 2009 ASC payment rates for the covered surgical procedures subject to transitional payment (payment indicators ''A2'' and ''H8'' in Addendum AA) are based on a blend of 50 percent of the CY 2007 ASC payment weight for the procedure and 50 percent of the CY 2009 fully implemented ASC weight before scaling for budget neutrality, calculated according to the standard methodology. 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 for 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 CY 2009 payment rate displayed in the ''CY 2009 Second Year Transition Payment'' column, each ASC payment weight in the ''CY 2009 Second Year Transition Payment Weight'' column was multiplied by the CY 2009 ASC conversion factor of $41.393. The conversion factor includes a budget neutrality adjustment for changes in the wage index. Items and services with a predetermined national payment amount, such as separately payable drugs and biologicals which are displayed in Addendum BB, may not show a relative payment weight. The ''CY 2009 Second Year Transition Payment'' column displays the CY 2009 national unadjusted ASC payment rates for all items and services. The CY 2009 ASC payment rates for separately payable drugs and biologicals are based on ASP data used for payment in physicians' offices in October 2008.

Comment: Several commenters requested that CMS display in Addendum AA the fully implemented ASC payment rates. They stated that it would be helpful to them to see what ASC payment rates would be expected to look like once the transitional period is over.

Response: The fully transitioned ASC payment rates do not represent what the payment rates would be once the transitional period is over. They represent what the payment rates would be in CY 2009 in the absence of a transition. However, in response to these requests by these commenters, we will make the fully transitioned CY 2009 ASC payment weights available on the CMS Web site at *http://www.cms.hhs.gov/ASCPayment/* shortly after the publication of this final rule with comment period.

After consideration of the public comments received, we are finalizing our CY 2009 proposal to display the updated CY 2009 ASC payment rates for covered surgical procedures and covered ancillary services in Addenda AA and BB, respectively, to this final rule with comment period. We also will make available on the CMS Web site what the ASC payment weights would be in CY 2009 without the transition.

XVI. Reporting Quality Data for Annual Payment Rate Updates

A. Background

1. Reporting Hospital Outpatient Quality Data for Annual Payment Update

Section 109(a) of the MIEA–TRHCA (Pub. L. 109–432) amended section 1833(t) of the Act by adding a new subsection (17) that affects the payment rate update 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, 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 section 1833(t)(17)(B) of the Act will incur a reduction in their annual payment update factor by 2.0 percentage points. 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. Sections 1833(t)(17)(C)(i) and (ii) of the Act require the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that these measures reflect consensus among affected parties and, to the extent feasible and practicable, include measures set forth by one or more national consensus building entities. The Secretary is not prevented from selecting 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 for the IPPS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program. 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 available to the public. Such procedures must give hospitals the opportunity to review data before these data are released to the public.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68189), we indicated our intent to establish an OPPS payment program modeled after the current IPPS RHQDAPU program. We stated our belief that the quality of hospital outpatient services would be most appropriately and fairly rewarded through the reporting of quality measures developed specifically for application in the hospital outpatient setting. We agreed that assessment of hospital outpatient performance would ultimately be most appropriately based on reporting of hospital outpatient measures developed specifically for this purpose. We stated our intent to implement the full OPPS payment rate update beginning in CY 2009 based upon hospital reporting of quality data beginning in CY 2008, using effective measures of the quality of hospital outpatient care that have been carefully developed and evaluated, and endorsed as appropriate, with significant input from stakeholders.

The amendments to the Act made by section 109(a) of the MIEA–TRHCA are consistent with our intent and direction outlined in the CY 2007 OPPS/ASC final rule with comment period. Under these amendments, we were statutorily required to establish a program under which hospitals would report data on the quality of hospital outpatient care using standardized measures of care in order to receive the full annual update to the OPPS payment rate, effective for payments beginning in CY 2009. We refer to the program established under these amendments as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP). In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66860), we established a separate reporting program, and adopted quality measures that were deemed appropriate for measuring hospital outpatient quality of care that reflected consensus among affected parties, and were set forth by one or more national consensus building entities. Validation, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66871), is intended to provide assurance of the accuracy of the hospital abstracted data. A data validation requirement was not implemented for purposes of the CY 2009 annual payment update. In the CY 2009 OPPS/ASC proposed rule (73 FR 41546), we proposed to implement validation requirements that will apply beginning with the CY 2010 payment determinations. As discussed in section XVI.E.3.a. of this preamble, we are not adopting our validation proposal, but instead are adopting a voluntary test validation process for CY 2010.

In reviewing the measures currently available for care in the hospital outpatient settings, we continue to believe that it would be most appropriate and desirable to use

measures that specifically apply to the hospital outpatient setting. In other words, we do not believe that we should simply, without further analysis, adopt the IPPS RHQDAPU program measures as the measures for the HOP QDRP. Nonetheless, we note that section 1833(t)(17)(C)(ii) of the Act allows the Secretary to ''[select] measures that are the same as (or a subset of) the measures for which data are required to be submitted'' under the IPPS RHQDAPU program. In the CY 2009 OPPS/ASC proposed rule (73 FR 41540), we invited public comment on whether we should select for the HOP QDRP some or all measures from the current RHQDAPU program measure set that apply to the outpatient setting.

Comment: One commenter recommended that CMS move beyond pay-for-reporting toward pay-for-performance so that payment updates depend on empirical results from quality data, not on whether the data are submitted, and encouraged CMS to request this authority from Congress.

Response: We thank the commenter for sharing this suggestion for future program directions.

Comment: One commenter requested that CMS not penalize hospitals by cutting their payment update if hospitals can demonstrate that they are currently working to comply with the reporting requirements, but do not yet have the infrastructure to fully comply.

Response: We understand that setting up a new reporting program has challenges. We recognize that, unlike the RHQDAPU program, the reporting of hospital outpatient data did not have the benefit of existing reporting systems. However, section 109(a) of MIEA–TRHCA requires that the reporting system apply to payment for services furnished on or after January 1, 2009. In order to assist hospitals in meeting this requirement, we have provided support to hospitals with the provision of a data reporting tool, known as the CMS Abstraction and Reporting Tool for Outpatient Department measures (CART–OPD), which is available at the QualityNet Web site (*http://www.qualitynet.org*). We also have delayed the submission of data as much as possible. As required by statute, hospitals failing to report the required data will be subject to a reduction in their annual payment update.

Comment: One commenter questioned the intent of the quality data reporting program, how fairness for all providers is achievable, and how payment and quality are linked with respect to hospitals and physicians. The commenter stated that hospitals have been singled out and unfairly penalized for services and care they have limited ability to control.

Response: We are required to implement the amendments made to the Act by section 109(a) of the MIEA–TRHCA regarding data for measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings. The HOP QDRP program provides an incentive to hospitals to report quality data. Under the statute, there is no penalty applied to hospitals based on the quality of the services provided.

Comment: Several commenters suggested that critical access hospitals (CAHs) be allowed to voluntarily report outpatient hospital data. Some of these commenters expressed the desire that CMS address this issue formally in some manner, including suggesting addressing this issue in OPPS rulemaking.

Response: We thank the commenters for their support of having CAHs voluntarily report outpatient data. However, because CAHs are not subject to the OPPS or the revised ASC payment system, we do not, at this time, plan to address this issue in the OPPS/ASC rulemaking process.

Comment: Several commenters suggested that CMS evaluate RHQDAPU program measures for their suitability for outpatient setting. The commenters recommended re-specification and refinement for the outpatient setting of inpatient measures determined suitable upon testing. The commenters suggested that the following specific RHQDAPU program measures were potentially appropriate for use in the outpatient setting: [Acute Myocardial Infarction] AMI–2 (Aspirin prescribed at discharge); AMI–6 (Beta blocker at arrival); AMI–5 (Beta blocker prescribed at discharge); HF–1 (Discharge instructions); and PN–3b (Blood culture performed before first antibiotic received in hospital).

Response: We welcome these suggestions. We support the use of similar measures in different settings to promote broader and more consistent attention to specific processes of care. We also agree that such efforts of aligning inpatient and outpatient measures can allow for greater efficiencies in data collection and submission by hospitals across health care settings. We note that some of the existing OPPS measures focus on the same processes of care included in similar IPPS measures. We will investigate the suitability of the IPPS measures suggested and other measures currently in use in CMS reporting programs for future use in the outpatient setting.

After consideration of the public comments received, we are finalizing measures that specifically apply to services furnished in the hospital outpatient setting. In the future, we will consider adapting more measures from the current IPPS RHQDAPU program measure set for use in the OPPS measures set.

2. Reporting ASC Quality Data for Annual Payment Update

Section 109(b) of the MIEA–TRHCA amended section 1833(i) of the Act by redesignating clause (iv) to clause (v) and adding new sections 1833(i)(2)(D)(iv) and 1833(i)(7) to the Act. These amendments may affect ASC payments for services furnished in ASC settings on or after January 1, 2009. Section 1833(i)(2)(D)(iv) of the Act authorizes the Secretary to implement the revised payment system for services furnished in ASCs (established under section 1833(i)(2)(D) of the Act), ''so as to provide for a reduction in any annual update for failure to report on quality measures. * * *''

Section 1833(i)(7)(A) of the Act authorizes the Secretary to 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 ASC update for a subsequent calendar 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 sections 1833(t)(17)(B) through (E) of the Act, summarized above, shall apply to ASCs. We did not implement an ASC quality reporting program for CY 2008 (72 FR 66875).

We refer readers to section XVI.H. of this final rule with comment period for a discussion of our decision to implement ASC quality data reporting in a later rulemaking.

3. Reporting Hospital Inpatient Quality Data for Annual Payment Update

Section 5001(a) of Public Law 109–171 (DRA) set out the current requirements for the IPPS RHQDAPU program. We established the RHQDAPU program in order to implement section 501(b) of Public Law 108–173 (MMA). The program builds on our ongoing voluntary Hospital Quality Initiative.

The Initiative is intended to empower consumers with quality of care information so that they can make more informed decisions about their health care while also encouraging hospitals and clinicians to improve the quality of their care. Under the current statutory provisions found in section 1886(b)(3)(B)(viii) of the Act, the IPPS annual payment update for ''subsection (d)'' hospitals that do not submit inpatient quality data in a form and manner, and at a time specified by the Secretary is reduced by 2.0 percentage points.

We used an initial ''starter set'' of 10 quality measures for the IPPS RHQDAPU program under section 501(b) of Public Law 108–173 and have expanded the measures as required under section 1886(b)(3)(B)(viii)(III), (IV) and (V) of the Act, as added by section 5001(a) of Public Law 109–171. We initially added measures as a part of the annual IPPS rulemaking process. In response to public comments asking that we issue IPPS RHQDAPU program quality measures and other requirements as far in advance as possible, we also have used the OPPS annual payment update rulemaking process to adopt IPPS RHQDAPU program measures and requirements. In the CY 2007 OPPS final rule (71 FR 68201), we included six additional IPPS RHQDAPU program quality measures for the FY 2008 update. In the CY 2008 OPPS/ASC final rule with comment period, we added two additional National Quality Forum (NQF)-endorsed quality measures to the IPPS RHQDAPU program (72 FR 66875–66876).

In the FY 2009 IPPS proposed rule (73 FR 23642), we proposed to retire one of the existing 30 quality measures and to add 43 additional quality measures for the FY 2010 payment update (73 FR 23647, 23651). In the FY 2009 IPPS final rule (73 FR 48604), we retired one existing measure, but only adopted 13 of the proposed additional 43 measures (73 FR 48609). We indicated that we intended to adopt two additional measures in this CY 2009 OPPS/ASC final rule with comment period, but only if the measures were endorsed by a national consensus-based entity such as the NQF (73 FR 48611). The NQF is a voluntary consensus-based standard-setting organization established to standardize health care quality measurement and reporting through its consensus development process. Under section 1886(b)(3)(B)(viii)(V) of the Act, we are required to add measures that reflect consensus among affected parties and, to the extent feasible and practicable, include measures set forth by one or more national consensus building entities. As discussed in section XVI.I. of this CY 2009 OPPS/ASC final rule with comment period, we are adding two additional quality measures to the IPPS RHQDAPU program for FY 2010 because the NQF has endorsed these measures.

B. Hospital Outpatient Quality Measures for CY 2009

For the CY 2009 annual payment update, we required HOP QDRP reporting using seven quality measures—five Emergency Department (ED) AMI measures plus two Perioperative 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.

The five ED–AMI measures capture the quality of care for acute myocardial infarction in the outpatient setting in hospital EDs, specifically for those adult patients with AMI who are treated and then transferred to another facility for further care. Outpatients treated for AMI receive many of the same interventions as patients who are evaluated and admitted at the same facility. Three (ED–AMI–1 [OP–4], ED–AMI–3 [OP–2] and ED–AMI–5 [OP–3]) of these five measures, except for their limitation to outpatients (transferred patients), are equivalent to those currently reported under the IPPS RHQDAPU program for admitted patients, and are published on the Hospital Compare Web site at: *http://www.HospitalCompare.hhs.gov.* The other two ED–AMI measures encompass timely delivery of care and transfer for patients presenting to a hospital with an AMI who are not admitted but transferred to another facility. Transferred AMI patients are currently not included in the calculation of the inpatient AMI measures because of the limitation of the RHQDAPU program measures to inpatients.

In addition to the five ED–AMI measures, we required reporting of two measures related to surgical care improvement. These two surgical care improvement measures derived from the Physician Quality Reporting Initiative (PQRI) are directly related to interventions provided in the outpatient setting and address selection and timely administration of prophylactic antibiotics for surgical infection prevention, similar to measures in the IPPS RHQDAPU program.

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 66860), we required that subsection (d) hospitals paid under the OPPS submit data on the following seven measures as designated below, effective for hospital outpatient services furnished on or after April 1, 2008:

CY 2009 HOP QDRP QUALITY MEASURES

ED–AMI–1—Aspirin at Arrival.
ED–AMI–2—Median Time to Fibrinolysis.
ED–AMI–3—Fibrinolytic Therapy Received within 30 Minutes of Arrival.
ED–AMI–4—Median Time to Electrocardiogram (ECG).
ED–AMI–5—Median Time to Transfer for Primary PCI.
PQRI #20: Perioperative Care: Timing of Antibiotic Prophylaxis.
PQRI #21: Perioperative Care: Selection of Perioperative Antibiotic.

C. Quality Measures for CY 2010 and Subsequent Calendar Years and the Process To Update Measures

1. Quality Measures for CY 2010 Payment Determinations

In the CY 2009 OPPS/ASC proposed rule (73 FR 41541), for CY 2010, we proposed to require continued submission of data on the existing seven measures discussed above and to adopt four imaging measures. We proposed to designate the existing seven measures as follows:

CY 2009 QUALITY MEASURES WITH PROPOSED CY 2010 DESIGNATIONS

Current designation	Proposed quality measure designation
ED–AMI–2	OP–1: Median Time to Fibrinolysis.
ED–AMI–3	OP–2: Fibrinolytic Therapy Received Within 30 Minutes.
ED–AMI–5	OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention.
ED–AMI–1	OP–4: Aspirin at Arrival.
ED–AMI–4	OP–5: Median Time to ECG.

CY 2009 QUALITY MEASURES WITH PROPOSED CY 2010 DESIGNATIONS—Continued

Current designation	Proposed quality measure designation
PQRI #20	OP–6: Timing of Antibiotic Prophylaxis.
PQRI #21	OP–7: Prophylactic Antibiotic Selection for Surgical Patients.

Comment: Commenters supported the current HOP QDRP measures, which were seen as having a positive impact on quality of care. One commenter recommended limiting the measures for 2009 to those seven that are currently implemented.

Response: We agree that the current HOP measures are important to the quality of care patients receive in the HOPD and will continue their collection. We also are committed to broadening the scope of measurement for the HOP QDRP and, therefore, have proposed additional measures for the CY 2010 annual payment update and have solicited comments on measures being considered for implementation in future years.

Comment: One commenter did not support the proposed quality measure OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention (formerly, ED–AMI–5). The commenter stated that this measure would result in additional burden to hospitals without an increase in meaningful quality data.

Response: We believe that, when percutaneous intervention (PCI) is indicated, timely transfer of patients is an important aspect of quality of care in the hospital outpatient setting; hence our inclusion of this measure in the HOP QDRP measure set. National guidelines recommend the prompt initiation of PCI in patients presenting with ST-segment elevation myocardial infarction. The early use of primary PCI in patients with acute myocardial infarction who present to the ED with ST-segment elevation or LBBB results in a significant reduction in mortality and morbidity. Despite these recommendations, few eligible older patients hospitalized with AMI receive primary angioplasty in a timely manner. Patients transferred for primary PCI rarely meet recommended guidelines for door-to-balloon time, which under current American College of Cardiology/American Hospital Association recommendations is 90 minutes or less. Therefore, we believe that reporting on this measure will increase meaningful quality of care data.

Comment: One commenter did not support the current HOP QDRP measure set and perceived the set as not adequately measuring the breadth of coverage in the ED or the HOPD. The commenter suggested that CMS adopt cross-cutting measures, outcomes measures, and process measures that are correlated to outcomes.

Response: Because CY 2008 was the first year of the OPPS reporting program, we decided to limit the number of HOP QDRP reporting requirements. In future years, we anticipate that the scope of outpatient services covered by measures will increase. For HOP QDRP reporting for CY 2009, we are adding four imaging efficiency measures, which add another topic to the HOP QDRP measure set. We support the development and implementation of cross-cutting, outcome, and process measures that are correlated to outcomes and intend to consider such measures for future rulemaking.

Comment: Several commenters expressed concern that the current HOP QDRP measure set (OP–1 to OP–7) was not fully field-tested for its use in HOP QDRP. They urged CMS to fully test in order to identify and correct operational issues before data validation on the CY 2009 measures begin. One commenter expressed concern over frequent changes in the consensus base, citing the reversal of consensus on whether prophylaxis is necessary for bunion surgery, and recommended that new quality measures be based in valid clinical studies.

Response: The HOP QDRP measures were selected and implemented as required under section 1833(t)(17) of the Act. While the short timeframe available to implement the program as required by statute did not permit extensive field testing prior to implementation in CY 2008, we did conduct limited pilot testing on a small convenience sample. Specifically, the measure specifications were used to collect data from 189 medical records in Oklahoma and Illinois. Additionally, these seven HOP QDRP measures are NQF-endorsed and are supported by clinical evidence. The measures have been in effect for services furnished on or after April 1, 2008 and hospitals have been submitting data successfully to the OPPS Clinical Warehouse. We plan to analyze the data collected under the HOP QDRP to evaluate the seven initial HOP QDRP measures and to address operational issues in data collection for these already implemented measures before CY 2009 validation. We also believe that our plan to conduct a voluntary test validation on these measures as outlined in section XVI.E.3.a. of this preamble will provide sufficient time to assess the relevant issues for these measures, and will provide both CMS and the sampled hospitals with valuable feedback for measure maintenance purposes during this voluntary validation test period. We have a measures development contractor working to maintain and refine the measures specifications as needed. In terms of the comment on consensus base of the measures, we intend to utilize our measure maintenance processes and, as appropriate, consensus building entities such as the NQF to address changes in the clinical evidence base that may require changes to measure specifications that will be described in the CMS Hospital Outpatient Quality Measures Specifications Manual (Specifications Manual). CMS believes that, while this may result in changes that occur more frequently than the usual 3 year re-evaluation intervals, such flexibility is necessary to accommodate changes in the clinical evidence base informing these measures.

After consideration of the public comments received, we are finalizing for continued data collection in CY 2009 for the CY 2010 annual payment update the following seven current HOP QDRP measures, redesignated as discussed above: (1) OP–1: Median Time to Fibrinolysis; (2) OP–2: Fibrinolytic Therapy Received Within 30 Minutes; (3) OP–3: Median Time to Transfer to Another Facility for Acute Coronary Intervention; (4) OP–4: Aspirin at Arrival; (5) OP–5: Median Time to ECG; (6) OP–6: Timing of Antibiotic Prophylaxis; and (7) OP–7: Prophylactic Antibiotic Selection for Surgical Patients.

The four imaging measures that we proposed to adopt beginning with the CY 2010 payment determination are claims-based measures that CMS would calculate using Medicare Part B claims data without imposing on hospitals the burden of additional chart abstraction. For purposes of the CY 2010 payment determination, CMS would calculate these measures using CY 2008 Medicare administrative claims data.

The proposed imaging measures are based on clinical evidence that they promote efficient and high quality patient care. Efficient healthcare is that which neither underutilizes nor over utilizes healthcare resources. This approach to defining efficiency is supported by the observation of widespread process variation in healthcare that is not associated with variation in outcome. The Institute of Medicine has identified efficiency as an important quality aim. However, despite the identification of efficiency as an important factor in the provision health care, there currently are few healthcare efficiency quality measures available. MedPAC's description of the rapid growth in the volume of imaging services in 2000 as compared to 2006, coupled with the significant level of these services rendered under the OPPS suggests that imaging is an area to investigate with regard to efficiency. In the CY 2009 OPPS/ASC proposed rule (73 FR 41541), we proposed four imaging measures that measure high quality, efficient use of services for the hospital outpatient setting.

PROPOSED ADDITIONAL QUALITY MEASURES FOR CY 2010

Topic	Measure
Imaging Efficiency	OP–8: MRI Lumbar Spine for Low Back Pain. OP–9: Mammography Follow-up Rates. OP–10: Abdomen CT—Use of Contrast Material: • OP–10: CT Abdomen—Use of Contrast Material. • OP–10a: CT Abdomen—Use of Contrast Material excluding calculi of the kidneys, ureter, and/or urinary tract. • OP–10b: CT Abdomen—Use of Contrast Material for diagnosis of calculi in the kidneys, ureter, and/or urinary tract. OP–11: Thorax CT—Use of Contrast Material.

We invited public comment on these four proposed imaging measures, which had been submitted to the NQF for consideration.

Comment: Several commenters supported the proposed imaging efficiency measures. The commenters agreed that these claims-based imaging efficiency measures avoid increased data collection burden. One commenter was pleased that the proposed rule includes cancer related quality measures, in particular the mammography follow-up rates. One commenter agreed that ''combined studies with and without contrast'' in thorax CT should be ordered infrequently and that this is an area where cost could possibly be reduced. One commenter was supportive of the use of claims data to gather information on OP–8: MRI Lumbar Spine for Low Back Pain, as the information is not available using chart abstraction. This commenter was also pleased that measure OP–8 is harmonized with the NCQA low back pain measure. One commenter, in support of measure OP–9: Mammography Follow-up Rates, stated that the measure has the potential to positively affect the quality of life and health of Medicare patients, and also believed that the measure supports the work of organizations such as the American Cancer Society Cancer Action Network.

Response: We thank these commenters for their supportive statements, and are adopting the four imaging efficiency measures in this final rule with comment period.

Comment: Several other commenters believed that the four new imaging efficiency measures are still in the developmental phase and have not yet received NQF endorsement nor have they been considered for adoption by the Hospital Quality Alliance (HQA). They urged CMS to not adopt the four imaging efficiency measures at this time and to reevaluate the measures at such time as essential measure specifications, NQF endorsement and AQA–HQA collaboration can be accomplished. One commenter stated that data specifications should be available when public comment is requested.

Response: We believe that the four new imaging efficiency measures meet the requirements of section 1833(t)(17)(C)(i) of the Act, as added by section 109(a) of MIEA–TRHCA, and we are adopting them in this final rule with comment period. Section 1833(t)(17)(C)(i) of the Act requires the Secretary to ''develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.'' We believe that these imaging efficiency measures are appropriate for the measurement of the quality of care furnished by hospitals in outpatient settings. The proposed imaging efficiency measures have gone through an extensive development process with broad stakeholder input incorporated throughout the development process. Specifically, the measures development process for the imaging efficiency measures included the convening of a Technical Expert Panel (TEP) by a contractor comprised of affected parties affiliated with hospitals, payers, practitioners from various medical specialties, consumers, as well as clinical, scientific, and performance measurement experts. The TEP was convened multiple times to identify, develop, and refine measures associated with an area requiring quality measurement. The TEP did not move forward measures for development upon which the TEP did not agree.

The measure development process also included a public comment period. The measures development contractor publicly posted the measure specifications during this time. In the future, we also will make relevant measure specifications available during public comment periods following proposed rulemakings. Comments during the measure development public comment period included supportive comments from many affected parties, including comments indicating that these measures are a timely and much needed addition to imaging efficiency measurement given the scarcity of such measures that have been set forth by a national consensus building entity, that they address areas of great epidemiologic relevance, and that they address the needs of affected parties for accountability and transparency for an area of increasing waste and inefficiency. These measures were modified based upon public comments received during the public comment period. Given this process, we believe that these measures are no longer in the development phase and are appropriate

for the measurement of quality of care furnished by hospitals in outpatient settings.

These measures also reflect consensus among affected parties, as required by section 1833(t)(17)(C)(i) of the Act. The proposed measures have been developed by the Secretary through a consensus-building process that included a broadly representative TEP and a public comment period, as discussed above. We believe that this statutory requirement is met when the development process for the completed measures reflects consensus of a broad representation of affected parties.

Finally, we believe the requirement that the measures developed by the Secretary, to the extent feasible and practicable, include measures set forth by one or more national consensus building entities is met, as required by section 1833(t)(17)(C)(i) of the Act. Two of the four imaging efficiency measures (OP–8 and OP–11) have been endorsed by NQF, a national consensus building entity. We note, however, that the statute does not require that each measure be endorsed by NQF or other national consensus building entities. Further, the statute does not require that the Secretary limit measures to those adopted by stakeholder organizations not meeting the requirements of voluntary consensus organizations under the National Technology Transfer and Advancement Act (NTTAA), such as the HQA or AQA. Moreover, we believe it is not feasible and practicable to adopt only imaging efficiency measures that have been endorsed by a national consensus building entity.

The measurement area of efficiency is currently in its infancy, and there are few measures available for adoption that have been set forth by a national consensus building entity, such as NQF. We have given consideration to measures that have been endorsed by NQF. However, except for the two efficiency measures included in this final rule with comment period, we did not find that these other measures meet program needs because other NQF-endorsed measures are not measures at the facility level or do not sufficiently address the quality aim of efficiency. For example, other NQF-endorsed measures may focus on documentation requirements and not efficiency. As the area of efficiency measurement matures, it will become more feasible and practicable to adopt additional measures that have been set forth by a national consensus building entity.

With respect to the proposed imaging efficiency measures, we believe that there are important factors involving patient safety weighing in favor of including these measures in the HOP QDRP, even if they have not been set forth by a national consensus building entity. Specifically, these measures address the unnecessary administration of contrast materials and the unnecessary radiation exposure resulting from unnecessary imaging studies. These measures fill a significant gap given the few existing imaging efficiency measures available at the outpatient facility level. Therefore, we are adopting these measures in this final rule with comment period.

Comment: Several commenters opposed the use of CY 2008 claims to calculate compliance with the imaging efficiency measures for the CY 2010 payment determination. The commenters also stated that the use of claims data assesses a facility's utilization of imaging services as opposed to assessing the practice of the ordering physician. Numerous commenters stated that all of the imaging efficiency measures seemed to be more appropriately used in assessing physician quality rather than that for the HOPD, because, the commenters argued, the four measures are all physician-driven. One commenter stated that it was unclear whether compliance is based on ''reporting'' through claims submission or whether compliance is based on an unknown performance rate.

Response: We use CY 2008 claims to calculate the imaging efficiency measures for the CY 2010 payment determination because the CY 2008 claims are the most current existing claims data available to us. We do not require any additional data submission from hospitals for these measures to satisfy the requirements of the HOP QDRP.

The four imaging efficiency measures that we proposed are for the HOP QDRP and measurement is at the facility level, not at the physician level. We believe that, because HOPDs are receiving payment for these imaging services under the OPPS, these data are appropriate for use in measuring HOPD quality of care. There is no requirement that hospitals must meet a particular performance score in order to satisfy the requirements of the HOP QDRP in regard to the imaging efficiency measures, just that the hospitals report the required information.

Comment: Several commenters stated that the collection of imaging efficiency measures was inappropriately named and that the measures were unadjusted utilization rates. One commenter stated that the selection of the MRI and CT measures has raised suspicion with imaging services staff that CMS' motive is cost reduction only.

Response: We disagree with the characterization of the measures as utilization rates. These measures were constructed using the definition of efficiency adopted by the IOM, and are intended to address waste and promote the efficient beneficial use of services. We received input from affected parties, such as hospitals and consumers, and received agreement from such parties that these are efficiency measures as defined by the IOM criteria, and that they measure imaging efficiency. We select HOP QDRP measures in order to provide hospitals with a greater awareness of the quality of care they provide and to provide actionable information for consumers to make more informed decisions about their health care providers and treatments. For the imaging measures, the focus is on hospitals and consumers reducing unnecessary exposure to radiation and contrast materials as a result of duplicative imaging services.

Comment: Several commenters were concerned that the billing data proposed for the imaging efficiency measures would include Medicare patients only, which they believed could distort the true picture of the delivery of imaging services.

Response: While the distribution of the rates may be different when calculated using Medicare claims only, Medicare claims comprise a substantial portion of total hospital outpatient claims for these services therefore we believe that the use of these claims data would not provide a distorted view of the delivery of imaging services in the outpatient setting. We would be interested in calculating measures based on all-payer claims data and may propose to collect such data in the future. However, collection of all-payer data presents additional infrastructure issues.

Comment: One commenter asked what administrative processes will be implemented for claims-based measures and whether the administrative claims data will undergo reliability testing or validation by CMS. The commenter was concerned that if a hospital does not submit a claim for payment, this could result in the loss of 2 percentage points of the OPPS annual payment update for the hospital. The commenter asked if there would be a review period for hospitals of the administrative data before it was released to the public.

Response: CMS employs a variety of measures to ensure the accuracy of coding for outpatient claims from the provider to postpayment levels. All Medicare providers are required to have compliance programs in place. At the claims processing level, edits are in

place to ensure that claims are completed in a manner consistent with payment policy, and prepayment edits may flag claims for review. At the postpayment level, a variety of entities are utilized to detect improper payments. Prior to public reporting, we will provide each hospital an opportunity to review its data. Hospitals should submit claims for services they have furnished in order to receive payment on the claims and to receive the full annual payment update.

Comment: Several commenters did not believe that the OP–8: MRI Lumbar Spine for Low Back Pain measure is ready for implementation, and even with further testing and improvement, this measure is more suitable for physicians who order imaging tests than to the HOPD that implement or furnish physician orders. Some commenters stated that the measure does not allow for consideration of over-the-counter (OTC) medications as an indicator of antecedent therapy. Several commenters stated that they were unclear as to what steps they should take to improve their performance on this measure. These commenters were uncertain if CMS believes that hospitals should refuse access to MRIs for low back pain for those patients and whether they should provide proof of antecedent conservative therapy. One commenter stated that this measure is potentially a dangerous incentive where it aims for reductions without qualifiers because there are cases of epidural abscesses as well as abdominal aortic aneurisms that present with low back pain. This commenter believed that using a less costly diagnostic approach will delay diagnosis and potentially cause harm to the patient. One commenter believed that there are factors such as the lack of provider documentation that may lead to the appearance of inappropriate MRI orders for low back pain, and believed that this measure would be burdensome for the hospital and should be directed at the clinician. One commenter also stated that it will be important to communicate what OP–8 portrays, and whether better quality is indicated by a higher or lower efficiency score, and whether there is an appropriate benchmark or rate.

Response: This measure has undergone a rigorous development process and has been endorsed by NQF for accountability at the facility level. Although we believe that the basis for the measure may be appropriately applied at the ordering physician level, it is also a facility measure as considered by the NQF and we believe that this measure is ready for implementation at the facility level.

There is evidence that a substantial portion of MRIs for low back pain are potentially not beneficial and do not lead to any modification of therapy based on the MRI results, especially when performed on the first visit prior to any attempt to diagnose or treat the patient through more conservative means. OP–8 measures the rate of usage of MRI for low back pain and it accounts for a 6-week window between the time of presentation with low back pain and the imaging service, during which time it is expected that any OTC or other antecedent therapy would have occurred. This measure does not establish absolute parameters for the use of imaging services, but rather identifies variations from norms for the efficient use of imaging services. The focus of the measure is not on increasing rates to 100 percent or reducing rates to 0 percent or any other values; rather, the focus is on promoting efficient use of imaging services.

As for the role of the hospital, the hospital has control over the use of the MRI machine. HOPDs can improve their efficiency because they are in a position to promote consultation between ordering physicians and the radiologists engaged by the HOPD, to communicate directly with the ordering physician as needed, and otherwise to educate and communicate with and engage the hospital medical staff and community physicians on the appropriate use of MRI for low back pain. CMS does not believe that hospital outpatient departments should refuse access to MRIs for low back pain. Further, we disagree that this measure provides an inappropriate incentive for reductions in MRI for low back pain or it encourages the inappropriate use of less costly diagnostic approaches. The intent of the measure is to assess the appropriateness of the imaging study and, if a less costly approach is equally or more effective than the MRI, the HOPD should employ the less costly approach.

Finally, while provider documentation is important, these measures will be calculated by CMS based solely on claims that have been submitted to Medicare by HOPDs. Thus, there would be no collection burden associated with the calculation of these measures at the hospital outpatient level.

Comment: Several commenters stated that they did not believe that the OP–11: Thorax CT—Use of Contrast Material measure should be implemented at this time because preliminary calculations of the measure rate found a relatively low use of combined studies. They believed it was unclear to what extent there is room for improvement on this measure. One commenter was concerned that undefined and nonstratified use of administrative data may push physicians to treat patients on guidelines, not on how the patient presents.

Response: Our claims-based evidence indicates that there is significant practice variation in the use of combined studies, indicating room for improvement, and in many instances, a high level of use of combined studies in outpatient settings. This measure seeks to identify practice variation in the use of combined Thorax CT, which may be considered inefficient. The focus of this measure is to help identify inefficient use of imaging studies and it is important because it addresses important patient safety concerns including the unnecessary administration of contrast materials and the unnecessary radiation exposure resulting from unnecessary imaging studies. The measure specifications and administrative data are defined and incorporate inclusion and exclusion criteria to stratify the populations being observed. Additionally, they have been endorsed by a national consensus building entity, the NQF, which reviews the possible unintended consequences of the measures on physician practice patterns. Also, the imaging efficiency measures are at a facility level and not a physician level.

Comment: Numerous commenters stated that OP–10: Abdomen CT—Use of Contrast Material measure should not be implemented as it is currently defined because there is a lack of evidence in the published literature to determine the appropriate use of contrast material for these patients. One commenter stated that the order for use of contrast material may be difficult to attribute to a specific physician as one may order contrast, but many rely on the radiologist to determine whether contrast is needed. One commenter stated this would be difficult to implement due to the vast exclusions and, therefore, this was not a good choice to introduce quality measures to the imaging area.

Response: We disagree that evidence does not exist in the published literature concerning the appropriate use of contrast material for these patients. Regarding difficulty in implementing this measure, we conducted an extensive claims analysis during the development and evaluation of this measure. The results of this analysis indicate that a significant pattern of variation among providers exists in the use of combination examinations in conjunction with an abdomen CT. We

are not attributing the measure to individual physicians, as the furnishing of the service and its measurement occur at the facility level and the measure will be calculated using outpatient hospital claims. Any ''vast exclusions'' would not impede implementation of this measure because it will be calculated by Medicare billing data which is already submitted by hospitals' outpatient departments, thus, not providing additional implementation burden to HOPDs.

Comment: Numerous commenters recommended that the imaging efficiency measures be reviewed by the AMA Physician Consortium for Performance Improvement (PCPI) because they believed this group was best qualified to consider the appropriateness of the measures for numerous health conditions. They also stated that OPPS measures that relate to physician performance should be aligned with physician measures utilized in the PQRI.

Response: Although the AMA–PCPI is an important and active developer of physician level quality measures, the AMA–PCPI is not a primary developer of facility level measures. However, in some instances, measures developed by the AMA–PCPI can be adapted for facility use as were the two surgical infection measures included in the current HOP QDRP set of measures. Members of the AMA–PCPI frequently contribute comments to other measures developers, including comments on the development of these facility level measures. Harmonizing measures across settings is desirable and we agree that it may be useful to examine opportunities to align measures in the future.

Comment: Several commenters expressed concern that the Mammography Follow-Up Rates imaging efficiency measure (OP–9) was not ready for implementation. These commenters believed there was a lack of consensus as to what the appropriate recall rate should be, and thus, it was unclear to them what rate the hospitals should be striving to achieve. One commenter stated that appropriate follow-up for a normal screening mammogram might be a phone call or letter from the provider. The commenter was concerned that existing claims data are not adequate for this purpose, and the state of the art of electronic health records is not sufficiently developed to allow a meaningful calculation of follow-up without extensive manual collection and reporting. One commenter stated that this information creates redundancy as the information is already collected for the American College of Radiologists and the commenter's State. Another commenter stated that this measure inappropriately makes the hospital responsible for both the provider and the patient. The commenter stated that an educational campaign through a public service announcement would be just as effective and would not require the hospital to invest more money in developing an automated method to inform patients that their mammogram is due.

Response: We believe that the Mammography Follow-Up Rates imaging efficiency measure is ready for implementation because it underwent a consensus-based development process that meets the statutory requirement for adoption of a measure, and includes testing and public comment. The imaging efficiency measure OP–9: Mammography Follow-up Rates does not seek to establish or identify a specific range within which follow-up rates must fall. There has been considerable research done on appropriate ranges and, during the development process, we also found a range of rates among hospitals. The measure will identify differing relative performance rates. We are not attempting to determine whether follow-up occurred in terms of notification, but rather seek to measure the degree to which a facility must repeat mammography imaging for its patients. We appreciate the fact that hospitals may be responding to a number of reporting requests or requirements. However, the HOP QDRP is a separate reporting program for hospitals receiving payment under the OPPS, and, at this time, HOP QDRP requirements cannot be met by reporting under other programs. Because the imaging efficiency measures are claims based, hospitals will not need to collect and submit additional data; they need only to submit claims for services for which they are to be paid under Medicare. We performed extensive claims analysis for this measure using Medicare claims and also other claims databases available, and our results indicate that it is appropriate, valid and reliable to calculate this measure using claims data. The measure carries significant epidemiologic relevance in that it is aimed at optimizing the use of an examination that carries a proven benefit in terms of quality and longevity of life. We agree that educational campaigns and public service announcements may be beneficial to Medicare beneficiaries. We do not believe that these programs would replace or should supplant quality of care measurement and public reporting of the HOP QDRP measures because the data collected for HOP QDRP includes all OPPS hospitals and are not limited to only certain States or voluntary participation as other programs are, thus making HOP QDRP a more comprehensive quality reporting program.

Comment: One commenter wanted to know whether measure OP–11: Thorax CT—Use of Contrast Material will answer the question of what medical benefit the administration of contrast material provides.

Response: The measure is intended to measure the efficient use of imaging services and not answer specific clinical questions.

Comment: One commenter wanted CMS to specify a benchmark for measure OP–8: MRI Lumbar Spine for Low Back Pain to assess the percentage of cases where MRI intervention altered the course of patient management.

Response: We do not have a predetermined benchmark for this measure. However, the range of performance, including national and State averages, will become available as we publicly report the information.

Comment: One commenter requested that CMS risk-adjust the data for what it believed to be a more accurate representation of the patient population of tertiary hospitals and academic medical centers.

Response: In general, process of care measures do not require the use of risk adjustment. Process of care measures reflect best practices and clinical guidelines that apply independent of the condition of the patient. When certain conditions or circumstances for which the particular intervention being measured would not be appropriate, these cases are removed from the denominator of the process of care measure.

Comment: One commenter stated that in the field, hospitals find the issue of overuse of imaging services is often provider specific for the services included in the four proposed imaging efficiency measures and that these measures, in the commenter's opinion, involve the hospital being the policing entity for accepting an order for MRI and CT scans. The commenter requested that CMS consider making the overuse of imaging services an issue for the PQRI rather than one for the hospital that receives the physician orders. Another commenter argued that imaging services are targeted for measures because of the expense to CMS rather than patient safety issues. The commenter stated that its imaging services providers voiced immediate objections to these measures because

these are revenue generating examinations, ordered by physicians that they have little control over, and the proposed imaging efficiency measures have little to do with quality and all to do with cost.

Response: In our response to an earlier commenter, we discussed the role of the hospital with respect to the use of imaging services it controls. We believe that the commenters understate considerably the effective roles hospitals can play in promoting the efficient use of imaging services. Further, we disagree with the commenters' statements that these measures are focused on cost or expenses rather than on patient safety. As discussed previously, the focus of the four proposed imaging efficiency measures is on reducing unnecessary exposure to radiation and contrast materials as a result of duplicative imaging services.

Comment: One commenter stated that CMS has inappropriately assumed that hospitals fail to provide quality care due to the number of imaging services they perform, when, in fact, according to the commenter, the hospitals are merely working with their physicians and following orders to provide high-quality health care to Medicare beneficiaries.

Response: America's Health Insurance Plans (AHIP) estimates that a range of 20 percent to 50 percent of high-technology diagnostic imaging for a variety of conditions fails to provide information that improves patient diagnosis and treatment and may be considered redundant or unnecessary (July 2008 monograph *http://www.ahip.org/content/default.aspx?docid=24057*). There is a growing interest in pursuing strategies that promote the appropriate use of imaging services, avoid redundancy and unnecessary exposure to radiation, reduce painful and wasteful follow-up procedures, and ensure that the patient is getting the right service the first time. As discussed above, hospitals can play a role in promoting the efficient use of imaging services.

Comment: One commenter stated that none of these measures relates to radiation oncology.

Response: We did not intend for these measures to focus on radiation oncology. These measures are intended to measure imaging efficiency.

After consideration of the public comments received and as discussed in the above responses to those comments, we are finalizing the following four imaging efficiency measures for the CY 2010 payment determination: (1) OP–8: MRI Lumbar Spine for Low Back Pain; (2) OP–9: Mammography Follow-up Rate; (3) OP–10: Abdomen CT—Use of Contrast Material; and (4) OP–11: Thorax CT—Use of Contrast Material. Adoption of these four measures into the HOP QDRP meets the requirements of section 1833(t)(17)(C)(i) of the Act that the measures are appropriate for measurement of quality of care furnished by hospitals in outpatient settings, reflect consensus among affected parties and, to the extent feasible and practicable, include measures set forth by a national consensus building entity. All four of the proposed imaging efficiency measures reflect consensus among affected parties as meeting IOM criteria of measuring efficiency in general, and imaging efficiency in particular. In addition, two of the imaging efficiency measures we are finalizing (OP–8 and OP–11) are NQF-endorsed. For program purposes, the technical specifications for these four new HOP QDRP measures will be published in the January 2009 Specification Manual located at *http://www.qualitynet.org.*

The measures for the 2009 HOP QDRP measurement set to be used for the CY 2010 payment determination are as follows:

2009 HOP QDRP Measurement Set To Be Used for 2010 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.

2. Process for Updating Measures

Although we adopt measures through the rulemaking process, in the CY 2009 OPPS/ASC proposed rule (73 FR 41541), we proposed to establish a subregulatory process that would allow us to update the technical specifications that we use to calculate those measures when we believe such updates are warranted based on scientific evidence and guidance from a national consensus building entity. We believe that the establishment of a subregulatory process is necessary so that the HOP QDRP measures are calculated based on the most up-to-date scientific and consensus standards. We also recognize that neither scientific advances nor updates to measure specifications made by a consensus building entity are linked to the timing of regulatory actions. An example of changes that would prompt us to update a measure would be a change in antibiotic selection and/or timing (see measures OP–6 and OP–7) based on updated clinical guidelines or best practices.

Therefore, we proposed that when a national consensus building entity updates the measure specifications for a measure that we have adopted for the HOP QDRP program, we would update our measure specifications for that measure accordingly. We would provide notification of the measure specification updates on the QualityNet Web site, *http://www.qualitynet.org,* and in the Specifications Manual no less than 3 months before any changes become effective for purposes of reporting under the HOP QDRP. We invited public comments on this proposal.

Comment: Several commenters supported issuing measure specification updates to reflect the current standard of care based on scientific evidence and in accordance with the latest specifications endorsed by a national consensus organization through a subregulatory process. They stated that use of measures based on the most up to date scientific evidence will best ensure that patients receive high quality and appropriate care.

Response: We appreciate these supportive statements to our proposal that when a national consensus building entity updates the measure specifications for a measure that we have adopted for the HOP QDRP program, we would update our measure specifications for that measure accordingly through a subregulatory process. National consensus building entities issue changes of a substantive nature to measures they have endorsed which may occur off-schedule from the rulemaking cycle, but which nonetheless carry clinical significance, warranting updates to measures using a subregulatory process. This subregulatory process is in addition to the existing technical updates that are routinely made and posted to QualityNet and which constitute technical business requirements for data submission such as updates to ICD–9 or HCPCS codes.

For measures that are not endorsed by a national consensus building entity, the measures would be updated through the subregulatory process based on scientific advances as determined necessary by CMS. Once measures have been adopted by the HOP QDRP

program there is a measure maintenance process that occurs where Technical Expert Panels that represent consensus among affected parties review the measure specifications and take into account changes in scientific evidence as they evaluate the measure specifications and make recommendations to refine them. Changes such as this have occurred using this subregulatory mechanism to date, and we believe that it should continue to occur using this mechanism. Changes made in this manner would reflect current consensus resulting from changes in science and clinical evidence, and changes in consensus for which public input is sought through a national consensus process.

Comment: Many commenters also agreed that 90 days notice prior to implementation is sufficient. One commenter recommended that CMS consider issuing notification through additional systems (such as CMS listserv groups) as well as through QualityNet notices and regularly scheduled changes to the Specifications Manual, and to consider providing notification about such changes 6 months prior to implementation rather than 3 months.

Response: We will update our measure specifications for a measure through a subregulatory process providing at least 3 months advance notice for changes. QualityNet and the regularly scheduled Specifications Manual updates are our primary mechanisms for communicating changes relating to technical aspects of the measures as well as changes consistent with those made as part of endorsement status that reflect current science and consensus. We will investigate supplementing this communication through other means as well. We agree that if changes to measures result in changes in the data elements to be submitted and, therefore, require significant system changes, hospitals would require sufficient time to accommodate such changes, which we believe will be satisfied with 6-months notice. However, if changes do not affect data elements to be submitted, we intend to provide no less than 3 months notification for the change, which we believe would be sufficient.

Comment: Numerous commenters urged CMS to utilize the rulemaking process to announce quality measure changes and make accompanying measure specification changes. While many commenters agreed that a subregulatory process would be appropriate for minor changes, the commenters expressed concern that use of a subregulatory process would not afford hospitals sufficient time to consider substantive changes or new measures, and that the formal regulatory process should be utilized in order to provide an opportunity for public input to such changes.

Response: We did not propose to adopt new measures using a subregulatory process. Rather, a subregulatory process will be used in order to maintain specifications for existing quality measures to be consistent with current science and consensus among affected parties. This measure maintenance process has occurred using this subregulatory mechanism to date, and we believe that it should continue to occur using this mechanism. Changes made in this manner would reflect current consensus resulting from changes in science and clinical evidence, and changes in consensus for which public input is sought through a national consensus process. The adoption of new outpatient measures will continue to be through an annual notice-and-comment rulemaking process. However, we will provide a 6-month notice for substantive changes to data elements that will require significant systems changes, such as the addition of required new data elements.

Comment: One commenter stated that, prior to linking measures to outpatient payment, there should be evidence that the measures have an impact on quality and outcome for patients treated in the outpatient setting, and that the services measures should be reevaluated each year so that areas that are no longer a problem can be removed from the list.

Response: As part of the measure development process, the HOP QDRP measures have undergone rigorous scrutiny for validity as indicators of outpatient quality of care. Measures that are implemented in this reporting program will undergo regular reevaluation every 3 years as part of the measure maintenance and reevaluation process. However, we also may decide upon reviewing measures to suspend measures from the reporting program, and these decisions would be announced during the annual rulemaking process. While improvability is an important criterion for measure selection, we do not limit measure selection solely to areas perceived as problem areas.

After consideration of the public comments received, we are finalizing the use of the subregulatory process described to ensure that the HOP QDRP measures are calculated based on the most up-to-date scientific and consensus standards. We will continue to release a HOPD Specification Manual every 6 months and addenda as necessary providing at least 3 months of advance notice for non-substantive changes such changes to ICD–9 and HCPCS codes and at least 6 months notice for substantive changes to data elements that will require significant systems changes.

3. Possible New Quality Measures for CY 2011 and Subsequent Calendar Years

In the CY 2009 OPPS/ASC proposed rule (73 FR 41542), we sought comment on possible new quality measures for CY 2011 and subsequent calendar years. The following table contains a list of 18 measures included within 9 measure sets from which additional quality measures could be selected for inclusion in the HOP QDRP. This table includes measures and measure sets that are part of clinical topics for which we currently do not require quality measure data reporting, such as cancer. We note that we also sought comment on some of these measures in the CY 2008 OPPS/ASC proposed rule. We sought public comment on the measures and measure sets that are listed below as well as on any possible critical gaps or missing measures or measure sets. We specifically requested input concerning the following:

- Which of the measures or measure sets should be included in the HOP QDRP for CY 2011 or subsequent calendar years?
- What challenges for data collection and reporting are posed by the identified measures and measure sets?
- What improvements could be made to data collection or reporting that might offset or otherwise address those challenges?

We solicited public comment on the following measure sets and measures for consideration in CY 2011 and subsequent calendar years.

MEASURES UNDER CONSIDERATION FOR CY 2011 AND SUBSEQUENT CALENDAR YEARS

Topic		Measure
Cancer	1	Radiation Therapy is Administered within 1 Year of Diagnosis for Women Under Age 70 Receiving Breast Conserving Surgery for Breast Cancer.*
	2	Adjuvant Chemotherapy is Considered or Administered within 4 Months of Surgery to Patients Under Age 80 with AJCC III Colon Cancer.*
	3	Adjuvant Hormonal Therapy for Patients with Breast Cancer.*
	4	Needle Biopsy to Establish Diagnosis of Cancer Precedes Surgical Excision/Resection.*
ED Throughput	5	Median Time from ED Arrival to ED Departure for Discharged ED Patients.
Diabetes	6	Low Density Lipoprotein Control in Type 1 or 2 Diabetes Mellitus.*
	7	High Blood Pressure Control in Type 1 or 2 Diabetes Mellitus.*
Falls	8	Screening for Fall Risk.*
Depression	9	Antidepressant Medication During Acute Phase for Patients with New Episode of Major Depression.*
Stroke & Rehabilitation	10	Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Reports.*
	11	Carotid Imaging Reports.*
Osteoporosis	12	Communication with the Physician Managing Ongoing Care Post Fracture.*
	13	Screening or Therapy for Women Aged 65 Years and Older.*
	14	Pharmacologic Therapy.*
	15	Management Following a Fracture.*
Medication Reconciliation	16	Medication Reconciliation.*
Respiratory	17	Asthma Pharmacological Therapy.*
	18	Assessment of Mental Status for Community Acquired Pneumonia.*

*One of the 30 measures included as ''under consideration'' in the CY 2008 OPPS/ASC proposed rule.

We welcomed suggestions regarding other additional measures and topics relevant to the hospital outpatient setting that we could use to further develop the measure set, and indicated that we were particularly interested in receiving comments on potential HOP QDRP measures that could be used to measure the quality of care in other settings (such as hospital inpatient, physician office, and emergency care settings) and, thus, contribute to improved coordination and harmonization of high-quality patient care.

Comment: One commenter strongly supported inclusion of measure 5, Median Time from ED Arrival to ED Departure for Discharged ED Patients. The commenter believed that this measure is reasonable for assessing patient delays in receiving ED care. The commenter also recommended inclusion of a companion measure, Median Time from ED Arrival to ED Departure for Admitted Patients, because this measure assesses ''boarding'' time in the ED. This measure was not included in the CY 2009 OPPS/ASC proposed rule. Further, the commenter suggested that these measures be stratified by psychiatric population, ED observation, transferred patients, and all others.

Response: We thank the commenter for its support of the inclusion of measure 5. The Median Time from ED Arrival to ED Departure for Admitted Patients was specified to collect data on patients in the inpatient population and, therefore, is not appropriate for the outpatient setting. In the FY 2009 IPPS proposed rule (73 FR 23652), we solicited comments on this measure as a possible measure to be used in the RHQDAPU program for FY 2011 and subsequent years. We appreciate the suggestion regarding the stratification of the measure. We intend to stratify both measures by psychiatric, observation, and transferred patients, and those other patients who do not meet the other stratification criteria.

Comment: Several commenters described the challenges for data collection and reporting resulting from the proposed measures, and stated CMS should assess the amount of chart review required for different populations.

Response: We are interested in minimizing the burden on hospitals associated with data collection and reporting. We have sought to address this by using claims-based measures, where appropriate, and we are evaluating the use of data from clinical data registries. In the case of the ED timing measures, these data are routinely collected by hospitals currently. In addition, we are evaluating the potential for such data to be submitted electronically from hospital information systems. We have assessed collection burden for each measure as a whole for the global population. There is no additional burden of chart review for the stratified populations, since there is no requirement for an additional or separate chart review for the stratified populations.

Comment: One commenter stated that some of the measures do not add value for consumers, citing its belief that measure 4, the percentage of time a needle biopsy was used in diagnosis, has nothing to do with an accurate diagnosis or appropriate treatment; and that measure 16, the medication reconciliation, does not measure medication errors or avoidable harm.

Response: We believe that these measures would be of use to consumers. Literature indicates that needle biopsy results in a lower incidence of re-excision, reduced number of total operations, and a shorter time to complete surgery compared with surgical biopsy. Medication reconciliation review promotes the examination of inpatient and outpatient differences in patient medication, which helps reduce medical errors and supports the provision of quality care to patients.

Comment: One commenter stated that future measures should be more specific in terms of size, volume of services, type and level of care, geographical regions, and electronic health record (EHR)-implementation status. The commenter also stated that related measures should be assessed for alignment across settings or under different conditions.

Response: We appreciate these suggestions for possible future consideration. We agree that alignment across settings is an important goal.

Comment: One commenter stated the measures are too similar to measures used in physician office setting and should be setting specific. Other commenters stated that several of the measures are better suited for the physician office rather than the HOPD, and the measures should be thoroughly field tested before implementation.

Response: We believe that these measures are specific to the HOPD

because HOP QDRP measures pertain to services payable under the OPPS system. These include a variety of hospital services, including ED, outpatient surgery, and imaging services. While we understand that hospital outpatient services, such as in a hospital outpatient clinic, may appear similar to the physician office setting, these procedures and care are furnished and paid for at the HOPD level; therefore, accountability at this level is appropriate. We agree that measures should be field tested before implementation, and strives to do so during the measures development process.

Comment: Several commenters were concerned that the measures proposed for use in CY 2011 or beyond did not have full NQF endorsement.

Response: We previously discussed the consensus requirements for the HOP QDRP program under section 1833(t)(17)(C) of the Act. Although we prefer measures that represent voluntary consensus standards, such as provided by NQF-endorsed measures, we also take into account other considerations, including the availability of adequate NQF-endorsed measures, to meet program requirements.

Comment: Several commenters suggested additional measurement topics and measures for future implementation in the HOP QDRP. These included:

- Healthcare-associated infections
- MRSA process of care measures
- Cross-cutting risk-adjusted measures
- Surgical site infection
- Appropriate hair removal for surgery patients
- Central line associated blood-stream infections and central line bundle compliance
- Claims based measures of infections after outpatient hospital procedures
- Data and measures from national data registries
- High-risk disease
- Post-fracture care
- Acute and chronic pain management
- Anticoagulant therapy safety and education
- PQRI CAD and osteoporosis measures
- Coordination of care
- ED AMI mortality
- Severe sepsis and septic shock management bundle
- Confirmation of endotracheal tube placement
- Overall cardiac care
- Use and overuse of cardiac CT
- Inappropriate use of percutaneous cardiac interventions
- Measures that can be collected via electronic health records (EHRs)
- ASC measures

Response: We appreciate these suggestions and will consider these topic areas for future implementation. We agree with the importance of actively working to move to a system of data collection based on submission of data from EHRs. To this end, we are engaged with HIT standards setting organizations to promote the adoption of the necessary standards for the HOP QDRP and for quality measures for other settings.

Comment: Numerous commenters stated that CMS should only select NQF-endorsed measures for the HOP QDRP, and should work with large stakeholder organizations such as HQA, PCPI, AHQA, AMA, QASC, and IHI to prioritize measurement areas and measure selection. Commenters suggested other selection criteria, such as national priority areas identified by HHS, and called for CMS to develop a framework for the selection of measures that includes public input, priority setting, consultation with other Federal agencies, NQF endorsement, field testing, and staggered implementation. Commenters also suggested that hospital inpatient measures adopted for the RHQDAPU program should be reviewed for applicability when selecting measures for the hospital outpatient setting, and that CMS should make specifications for new hospital outpatient measures available for review through QualityNet at the time they are proposed.

Response: We discussed above the requirements of section 1833(t)(17)(C) of the Act. We prefer to use measures that have been adopted by national consensus building entities when such measures are available and adequately meet program needs. Our measure selection is generally guided by Departmental and CMS priorities supplemented by stakeholder input. For example, we are examining measures currently used in our reporting programs in other settings for potential applicability to the outpatient setting and ways we can harmonize measures across settings. We value stakeholder input which we receive from a broad range of stakeholders. However, ultimately, measures are selected through notice-and-comment rulemaking reflecting input from the public at large. The input we consider is not limited to particular stakeholders or groups of stakeholders. We will make outpatient measure specifications available to the public during the public comment period for the proposed rule on the CMS Web site. In future proposed rules, we will provide the Web site address at which the technical specifications for future proposed measures will be available during the public comment period.

Comment: One commenter stated that hospital-acquired condition (HAC) measures are not ready for implementation in the outpatient setting because care in the outpatient setting is much more varied and much less life-threatening than in the inpatient setting and because coding is more difficult. The commenter believed that HAC measures are difficult to establish and prone to subjectivity.

Response: We have not proposed any HAC measures for the HOP QDRP; however, we will consider the commenter's concerns as we develop proposed measures for CY 2011 and subsequent years.

Based on the public comments received, we will consider the recommended topic areas as we develop new quality measures for CY 2011 and subsequent calendar years.

D. Payment Reduction for Hospitals That Fail To Meet the HOP QDRP Requirements for the CY 2009 Payment Update

1. Background

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 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 proposed rule (73 FR 41542), we discussed how the proposed payment reduction for failure to meet the administrative, data collection, and data submission requirements of the HOP QDRP will affect 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 will 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 CY 2009 OPPS will receive the full OPPS payment update without the reduction.

2. Reduction of OPPS Payments for Hospitals That Fail To Meet the HOP QDRP CY 2009 Payment Update Requirements

a. Calculation of Reduced National Unadjusted Payment Rates

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 is updated annually by the OPD fee schedule increase factor. The conversion factor is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to this final rule with comment period): ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' or ''X.'' We proposed 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. While services assigned to New Technology APCs, specifically APCs 1491 (New Technology-Level IA ($0–$10)) through 1574 (New Technology-Level XXXVII ($9,500–$10,000)), are assigned status indicator ''S'' or ''T,'' the payment rates for New Technology APCs are set at the midpoint of a cost-band increment, rather than based on the product of the OPPS conversion factor and the relative payment weight. Therefore, in the CY 2009 OPPS/ASC proposed rule (73 FR 41543), we proposed to exclude services assigned to New Technology APCs from the list of services that are 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. We note that we also proposed that the reduction would apply to brachytherapy sources for which we proposed to assign status indicator ''U'' (Brachytherapy Sources. Paid under OPPS; separate APC payment). Subsequent to issuance of the proposed rule, Congress enacted Public Law 110–275 (MIPPA). Section 142 of Public Law 110–275 specifically requires 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 would not be 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 are not updated by the OPD fee schedule increase factor. We refer readers to section VII. of this CY 2009 OPPS/ASC final rule with comment period for further discussion of payment for brachytherapy sources.

Comment: One commenter supported the CMS proposal to not apply payment and copayment reductions to New Technology APCs for hospitals that did not meet the requirements of the HOP QDRP.

Response: We appreciate the commenter's support. We believe that, because New Technology APC payments are set using the cost-band methodology described above, the statutory requirement would not apply the reduction to these APCs.

The conversion factor is also not used to calculate the OPPS payment rates for separately payable services that are assigned status indicators other than status indicators ''P,'' ''Q1,'' ''Q2,'' ''Q3,'' ''R,'' ''S,'' ''T,'' ''V,'' or ''X.'' These services include separately payable drugs and biologicals, separately payable therapeutic radiopharmaceuticals, pass-through drugs and devices and brachytherapy sources that are paid at charges adjusted to cost, and a few other specific services that receive cost-based payment. As a result, in the CY 2009 OPPS/ASC proposed rule (73 FR 41543), with the exception of brachytherapy sources, we also proposed that the OPPS payment rates for these services would not be reduced because the payment rates for these services are not calculated using the conversion factor and, therefore, the payment rates for these services are not updated by the OPD fee schedule increase factor. In the CY 2009 OPPS/ASC proposed rule (73 FR 41502), we proposed prospective payment based on median costs for brachytherapy sources and proposed to assign brachytherapy sources status indicator ''U'' but, subsequent to the issuance of the CY 2009 OPPS/ASC proposed rule, Congress enacted Public Law 110–275, which further extended the payment period for brachytherapy sources based on a hospital's charges adjusted to cost.

Comment: One commenter suggested that reducing payment and copayment for pharmacy services for hospitals that fail to meet the requirements of the HOP QDRP is excessively punitive.

Response: As described above, the market basket reduction would not apply to separately paid drugs and biologicals that are assigned status indicator ''K'' or to therapeutic radiopharmaceuticals, assigned status indicator ''H'' in this final rule with comment period, which are paid at charges adjusted to cost for CY 2009 based on the provisions of section 142 of Public Law 110–275. The market basket reduction for hospitals that fail to meet the reporting requirements would only apply to those services whose payment rates are calculated using the conversion 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, in the CY 2009 OPPS/ASC proposed rule, we proposed that, effective for services paid under the CY 2009 OPPS, CMS would 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). It is necessary to calculate a reduced market basket conversion factor for hospitals that fail to meet reporting requirements because section 1833(t)(17)(A)(i) of the Act requires a reduction of 2.0 percentage points from the market basket update for those hospitals. (We implemented this statutory requirement in regulations at 42 CFR 419.43(h).) For a complete discussion of the calculation of the OPPS conversion factor, we refer readers to section II.B. of this CY 2009 OPPS/ASC final rule with comment period. Therefore, we proposed to 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. Beginning January 1, 2009, the PRICER will calculate reduced national unadjusted payment rates that will be used as a basis for paying hospitals that fail to meet the requirements of the HOP QDRP by multiplying the national unadjusted payment rates by the reporting ratio. This will result 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. For CY 2009, we proposed a reporting ratio of 0.981, calculated by dividing the reduced conversion factor of $64.409 by the full conversion factor of $65.684. As stated above, the use of the reporting ratio is mathematically equivalent to the creation and application of a reduced conversion factor to the OPPS payment

weights. The final CY 2009 reporting ratio is 0.981, calculated by dividing the reduced conversion factor of $64.784 by the full conversion factor of $66.059.

To determine the reduced national unadjusted payment rates that would apply to hospitals that fail to meet their quality reporting requirements for the CY 2009 OPPS, we will multiply the final full national unadjusted payment rate in Addendum B to this CY 2009 OPPS/ASC final rule with comment period by the final reporting ratio of 0.981. For example, CPT code 11401 (Excision, benign lesion including margins, except skin tag (unless listed elsewhere) trunk, arms or legs; excised diameter 0.6 to 1.0 cm), is assigned to APC 0019, with a final national unadjusted payment rate of $295.69. Where a hospital fails to meet the reporting requirements of the HOP QDRP for the CY 2009 payment update, the reduced national unadjusted payment rate for that hospital would be $290.07 (the reporting ratio of 0.981 multiplied by the full national unadjusted payment rate for CPT code 11401).

We did not receive any public comments on our proposal for determining the reduced national unadjusted payment rates that would apply to hospitals that fail to meet their quality reporting requirements for the CY 2009 OPPS.

After consideration of the public comments received, we are finalizing our proposal, without modification, to apply the market basket update reduction to payments for all services calculated using a conversion factor through application of the reporting ratio. The final CY 2009 reporting ratio is 0.981, calculated by dividing the reduced market basket conversion factor of $64.784 by the full market basket conversion factor of $66.059.

b. Calculation of Reduced Minimum Unadjusted and National Unadjusted Beneficiary Copayments

Under the OPPS, we have two levels of Medicare beneficiary copayment for many services: the minimum unadjusted copayment, and the national unadjusted copayment. The minimum unadjusted copayment is always 20 percent of the national unadjusted payment rate for each separately payable service. The national unadjusted copayment is determined based on the historic coinsurance rate for the services assigned to the APC. Where the national unadjusted copayment is blank for an item or service listed in Addendum B to this CY 2009 OPPS/ASC final rule with comment period, the national unadjusted copayment is equal to the minimum unadjusted copayment. In general, under our longstanding copayment policy, the coinsurance percentage (the ratio of the copayment to the service payment) for a particular service may decline over time to a minimum of 20 percent but will never increase. This is consistent with the statute's intent that eventually all services paid under the OPPS would be subject to a 20-percent coinsurance percentage. We refer readers to section 1833(t)(3)(B)(ii) of the Act for the specific statutory language. For additional background on the standard OPPS copayment calculation, we refer readers to the CY 2004 OPPS final rule with comment period (68 FR 63458 through 63459).

For hospitals that receive the reduced OPPS payment for failure to meet the HOP QDRP requirements, we believe that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced copayment liability for Medicare beneficiaries. Similarly, we believe that it would be inequitable to the beneficiary and in conflict with the intent of the law (section 1833(t)(3)(B)(ii) of the Act) and our longstanding policy (68 FR 63458 through 63459) if the coinsurance percentage of the total payment for certain OPPS services to which reduced national unadjusted payment rates apply was to increase as a result of using the reduced conversion factor to calculate these reduced national unadjusted payment rates. Therefore, in the CY 2009 OPPS/ASC proposed rule (73 FR 41544), we proposed 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 the authority of section 1833(t)(2)(E) of the Act, which authorizes the Secretary to ''establish, in a budget neutral manner, * * * adjustments as determined to be necessary to ensure equitable payments'' under the OPPS.

We considered calculating the national unadjusted copayments and the minimum unadjusted copayments based on the reduced national unadjusted payment rates, using our standard copayment methodology. We found that, in many cases, the beneficiary's copayment amount would remain the same as calculated based on the full national unadjusted payment rate, although the total reduced national unadjusted payment rate would decline because of the reduction to the conversion factor. Therefore, in these cases, the ratio of the copayment to the total payment (the coinsurance percentage) would increase rather than decrease if we were to calculate copayments based on the reduced national unadjusted payment rates. For example, in the case of APC 0019 (Level I Excision/Biopsy), the full national unadjusted payment rate for CY 2008 is $274.13 and the national unadjusted copayment is $71.87 or 26 percent of the full national unadjusted payment rate for the APC. If the reduction were in effect for CY 2008, the reduced national unadjusted payment rate would be $268.65 but the national unadjusted copayment, if calculated under the standard rules, would continue to be $71.87, which represents 27 percent of the reduced national unadjusted payment rate. We believe that the increased coinsurance percentage that results from this methodology is contradictory to the intent of the statute that the coinsurance percentage would never increase and is also contradictory to our copayment rules that are intended to gradually reduce the percentage of the payment attributed to copayments until the national unadjusted copayment is equal to the minimum unadjusted copayment for all services.

To avoid this inconsistent result, in the CY 2009 OPPS/ASC proposed rule (73 FR 41544), we proposed to apply the reporting ratio to the national unadjusted copayment and the minimum unadjusted copayment to calculate the national unadjusted copayments that would apply to each APC for hospitals that receive the reduced CY 2009 OPPS payment update. This application of the reporting ratio would be to the national unadjusted and minimum unadjusted copayments as calculated according to § 419.41 of the regulations, prior to any adjustment for hospitals' failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers would thereby share in the reduction of payments to these hospitals. We believe that applying this copayment calculation methodology for those hospitals that fail to meet the HOP QDRP requirements would allow us to appropriately set the national unadjusted copayments for the reduced OPPS national unadjusted payment rates and would be most consistent with the eventual establishment of 20 percent of the payment rate as the uniform coinsurance percentage for all services

under the OPPS. In the CY 2009 OPPS/ASC proposed rule, we proposed to revise §§ 419.41, 419.42, and 419.43 to reflect this policy.

Comment: Some commenters supported the CMS proposal for beneficiaries and secondary payers to share in the payment reduction for hospitals that fail to meet the HOP QDRP requirements.

Response: We appreciate the support for our proposed policy. In order to ensure that beneficiaries and secondary payers do not pay a higher share of the reduced payment that results from a hospital's failure to meet the reporting requirements, we believe that a copayment calculation methodology that applies the reporting ratio to the national unadjusted copayment and the minimum unadjusted copayment is most appropriate.

After consideration of the public comments received, we are finalizing our proposal, without modification, for beneficiaries and secondary payers to share in the payment reduction for hospitals that fail to meet the HOP QDRP requirements. We also are finalizing our revisions to §§ 419.41, 419.42, and 419.43 of the regulations, without modification, to reflect this policy.

c. Treatment of Other Payment Adjustments

In the CY 2009 OPPS/ASC proposed rule (73 FR 41544), we proposed that all other applicable adjustments to the OPPS national unadjusted payment rates would 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 would 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, we proposed that outlier payments would continue to be made when the criteria are met. For hospitals that fail to meet the quality data reporting requirements, we proposed that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. We believe no changes in the regulation text would be necessary to implement this policy because using the reduced payment for these outlier eligibility and payment calculations is contemplated in the existing regulations at § 419.43(d). This proposal conforms to current practice under the IPPS in this regard. Specifically, under the IPPS, for purposes of determining the hospital's eligibility for outlier payments, the hospital's estimated operating costs for a discharge are compared to the outlier cost threshold based on the hospital's actual DRG payment for the case. For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.F. of this CY 2009 OPPS/ASC final rule with comment period.

We did not receive any public comments on this proposal and, therefore, are finalizing our proposal without modification.

E. Requirements for HOPD Quality Data Reporting for CY 2010 and Subsequent Calendar Years

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66869), we stated that in order to participate in the HOP QDRP for CY 2009 and subsequent calendar years, hospitals must meet administrative, data collection and submission, and data validation requirements. 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 would receive a reduction of 2.0 percentage points in their updates for the affected payment year.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41544), for payment determinations affecting the CY 2010 payment update, we proposed to implement the requirements listed below. Most of these requirements are the same as the requirements we implemented for the CY 2009 payment determination.

1. Administrative Requirements

To participate in the HOP QDRP, several administrative steps must be completed. These steps require the hospital to:

- Identify a QualityNet administrator who follows the registration process and submits the information to the appropriate CMS designated contractor. All CMS designated contractors will be identified on the QualityNet Web site. The same person may be the QualityNet administrator for both the IPPS RHQDAPU program and the OPPS HOP QDRP. This designation must be kept current and must be done, regardless of whether the hospital submits data directly to the CMS designated contractor or uses a vendor for transmission of data.
- Register with QualityNet regardless of the method used for data submission.
- Complete the Notice of Participation form if one has not been completed or if a hospital has previously submitted a withdrawal form. We remind hospitals that they do not need to submit another Notice of Participation form if they have already done so and they have not withdrawn from participation. At this time, the participation form for the HOP QDRP is separate from the IPPS RHQDAPU program and completing a Notice of Participation form for each program is required. Agreeing to participate includes acknowledging that the data submitted to the CMS designated contractor will be submitted to CMS and may also be shared with a different CMS contractor or contractors supporting the implementation of the HOP QDRP program. For HOP QDRP decisions affecting CY 2010 payment determinations, hospitals that share the same Medicare Provider Number (MPN), now known as the CMS Certification Number (CCN) must complete a single Notice of Participation form.

Hospitals with a newly acquired CCN and hospitals that are not participating in the CY 2009 HOP QDRP must send a completed paper copy of the Notice of Participation form to the appropriate CMS designated contractor in order to participate in the CY 2010 HOP QDRP. Hospitals with a newly acquired CCN must submit a Notice of Participation form no later than 30 days after receiving their new provider CCN. Hospitals that did not participate or withdrew from participation in the CY 2009 HOP QDRP must submit a Notice of Participation form by January 31, 2009 in order to participate in the CY 2010 HOP QDRP. We proposed for CY 2011 to implement an on-line registration form and eliminate the paper form. We invited public comment on this proposed change.

Comment: Commenters supported the use of an on-line registration form.

Response: We thank these commenters for their support for our proposal to use an on-line registration form. We are finalizing the use of an on-line registration form with the concomitant elimination of the paper form for the Notice of Participation requirement for CY 2011.

Hospitals with newly acquired CCNs, as well as hospitals that are not participating in the CY 2009 HOP QDRP, that do not properly submit a

Notice of Participation form for CY 2010 as described above will be deemed as non-participatory, will not be able to submit data to the OPPS Clinical Warehouse, and will be deemed as not meeting reporting requirements under the HOP QDRP for CY 2010. Hospitals that have previously completed a Notice of Participation form and subsequently wish to terminate participation in the HOP QDRP must submit a withdrawal form. We did not receive comments on these proposed requirements.

After consideration of the public comments received and as discussed above, we are finalizing these administrative requirements as proposed.

2. Data Collection and Submission Requirements

In the CY 2009 OPPS/ASC proposed rule (73 FR 41545), we proposed that, to be eligible for the full OPPS payment update in CY 2010, hospitals must:

- Collect data required for the CY 2010 measure set that are finalized in this CY 2009 OPPS/ASC final rule with comment period and that will be published and maintained in the Specifications Manual that can be found at: *http://www.qualitynet.org.*We proposed that it will not be necessary 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, we proposed that the hospital will be allowed to sample cases and submit data for these sampled cases rather than submitting data from all eligible cases. We proposed that this sampling scheme will be set out in the Specifications Manual at least four months in advance of required data collection.

In addition, in order to reduce the burden on hospitals that treat a low number of patients who meet the submission requirements for a particular quality measure, we proposed that beginning with services furnished on or after January 1, 2009, hospitals that have five or fewer claims (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter will not be required to submit patient level data for the entire measure topic for that quarter. However, hospitals would still be required to submit aggregate measure population and sample size counts for the applicable measure topic as part of their quarterly data submissions.

- Submit the data according to the data submission schedule that will be available on the QualityNet Web site. HOP QDRP data will continue to be submitted through the QualityNet secure Web site (*https://www.qualitynet.org*). This Web site meets or exceeds all current Health Insurance Portability and Accountability Act requirements. Submission deadlines will be 4 months after the last day of each calendar quarter for measures finalized in the CY 2009 OPPS/ASC final rule with comment period. Thus, for example, the submission deadline for data for services occurring during the first calendar quarter of 2009 (January-March 2009) will be August 1, 2009, and the submission deadline for the second calendar quarter of 2009 (April-June 2009) will be November 1, 2009.
- Submit data to the OPPS Clinical Warehouse using either the CMS Abstraction and Reporting Tool for Outpatient Department measures (CART-OPD) or the tool of a third-party vendor that meets the measure specification requirements for data transmission to QualityNet. We proposed that hospitals must submit quality data through the QualityNet Web site to the OPPS Clinical Warehouse; a CMS-designated contractor will submit OPPS Clinical Warehouse data to CMS. Under current implementation, OPPS Clinical Warehouse data are not considered QIO data. However, it is possible that the information in the OPPS Clinical Warehouse may at some point be considered QIO information. If this occurs, OPPS Clinical Warehouse data may become subject to the stringent QIO confidentiality regulations in 42 CFR Part 480.

We proposed that hospitals are to submit data under the HOP QDRP on 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 will be made to assure that data elements common to both inpatient and outpatient settings are defined consistently (such as ''time of arrival'').

To be accepted by the CMS designated contractor, submissions would, at a minimum, need to be timely, complete, and accurate. Data submissions are considered to have been ''timely'' when data are submitted prior to the reporting deadline and have passed all CMS designated contractor edits. A ''complete'' submission is determined based on sampling criteria that will be published and maintained in the Specifications Manual to be found on the Web site at *http://www.qualitynet.org*, and must correspond to both the aggregate number of cases submitted by a hospital and the number of Medicare claims it submits for payment. To be considered ''accurate,'' submissions must pass validation, if applicable.

- Submit the aggregate numbers of outpatient episodes of care which are eligible for submission under the HOP QDRP. These aggregated numbers of outpatient episodes would represent the number of outpatient episodes of care in the universe of all possible cases eligible for data reporting under the HOP QDRP. 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.

Comment: One commenter asked what authority or rationale CMS had to require the submission of non-Medicare population counts. Some commenters questioned the requirement to submit aggregate Medicare population figures as CMS has this information from submitted Medicare claims. Some commenters stated that there was no demonstrable reason that aggregate population data are meaningful for quality improvement. Several commenters stated that the submitting of aggregate numbers of outpatient episodes of care is resource intensive. One commenter stated that because outpatient billing is not as standardized and structured as inpatient billing, without further field-testing to address the problem with population identification counts, unintended consequences with the reporting of incomplete and inaccurate data will result. One commenter suggested that, due to time required to recount cases with information systems limitations, a 10-percent variance be considered.

Response: Our authority for proposing that hospitals submit aggregate population data is found in section 1833(t)(17)(A) of the Act, which applies to hospitals as defined under section 1886(d)(1)(B) of the Act. That provision states that subsection (d) hospitals that do not report data required for the quality measures selected by the Secretary in the form and manner required by the Secretary will not receive the full payment rate update. We have stated that we intended to model the HOP QDRP after the RHQDAPU program for hospital inpatient services. The RHQDAPU program requires hospitals to comply with CMS/Joint Commission sampling requirements for submitting data. These requirements require hospitals to submit a random sample or a population count of their

caseloads for RHQDAPU program measures for both Medicare and non-Medicare patients. We do not currently have any patient population counts for non-Medicare patients. Because we do not have patient population counts for non-Medicare patients, we believe that this information would help us to better assess the completeness of hospital submitted HOP QDRP data for all treated patients. It is important to know how complete measurements are while considering them for quality improvement efforts or as results of quality improvement interventions. Further, the HOP QDRP measures are intended to provide the public with information on all patients treated in the outpatient hospital setting, including both Medicare and non-Medicare patients. We proposed to have hospitals report aggregate Medicare populations and sampling figures in order to assess whether hospitals are conducting appropriate sampling to what they believe their respective populations by measure to be.

However, we understand that outpatient data systems are more disparate and varied than inpatient data systems. We also realize that, in some cases, considerable effort has been required in order for a hospital to be able to determine how many patients it has who have received care meeting specifications. We are aware that there have been issues with translating HOP QDRP measure specifications to some hospital outpatient data systems. We acknowledge that there are issues with determining population counts based upon some existing measure specifications and share concerns regarding unintended consequences due to the reporting of incomplete and inaccurate information. Therefore, we are making the reporting of aggregate population figures voluntary (Medicare and non-Medicare) and not a requirement for payment decisions affecting the CY 2010 payment update. We emphasize that we are making this requirement voluntary only for data reported for CY 2009 to be used for the CY 2010 payment update. We intend to check reporting of Medicare claims in order to supply information to hospitals on their efforts to fully collect quality measure data on all eligible Medicare cases, but will not make any payment decisions affecting the CY 2010 payment update contingent on any comparisons made of CMS and population figures supplied voluntarily by hospitals.

Comment: Several commenters supported CMS' proposal to allow hospitals that have five or fewer claims (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter to not be required to submit patient level data for the entire measure topic for that quarter. The commenters believed that this approach is a sensible way to reduce the reporting burden on hospitals with a very small number of cases. However, commenters believed that hospitals should always be able to voluntarily report on quality measures if they want to do so.

Response: We appreciate the commenters' support. This proposal strives to minimize the reporting burden for hospitals with small patient caseloads. We welcome voluntary data submission by hospitals with smaller than the minimum number of cases. As we discussed above, the reporting of population figures by all hospitals will be voluntary.

Comment: One commenter suggested that the minimum number of claims to exempt a hospital from reporting be raised to 10 claims per quarter because 10 is still a small sample and should not be used to determine the annual payment update, nor be publicly reported when a statistical sample size is greater than 25.

Response: We selected more than 5 cases per quarter (more than 20 cases per year) as the minimum threshold to ensure that the vast majority of hospitals with sufficient caseload would be required to submit data, while easing the burden on hospitals whose patient counts were too small to reliably predict hospital performance. We have selected a quarterly basis for the minimum threshold as data reporting requirements are on a quarterly basis. We acknowledge that there may be some hospitals that may have smaller, fluctuating case number such that there are less than five cases one quarter and more than 5 another, but believe that these hospitals will be few. We believe that hospital level performance can be reliably estimated with 20 to 30 cases reported annually, consistent with commonly used statistical sampling practice (for reference, see Wilson Van Voorhis, Carmen R. and Morgan, Betsey L. (2007) Understanding Power and Rules of Thumb for Determining Sample Sizes, Tutorials in Quantitative Methods for Psychology, volume 3(2), pages 43 to 50). We believe that the more than five cases quarterly threshold is a fair, consistent, and easily understandable requirement that would not reduce the amount of reliable data publicly reported. It is likely that the vast majority of hospitals affected by this requirement would not have sufficient annual caseload for us to publicly report their data. We also chose the more than five cases quarterly threshold to be consistent with the RHQDAPU program for reporting hospital inpatient quality measure data.

Comment: One commenter argued that, if the proposed imaging measures were adopted, these data should be submitted at the patient level, regardless of whether or not the hospital has five or fewer claims for a measure within a certain set.

Response: The proposed imaging measures are Medicare claim-based measures. Therefore, we anticipate that hospitals (regardless of the number of claims for a measure within a certain measure set) will submit claims for these services because they will want to receive Medicare payment. Because we proposed to calculate these measures using CY 2008 Medicare claims data, we would expect that most of such claims have been submitted for payment.

Comment: Some commenters that supported CMS' proposal to allow hospitals that have five or fewer claims (both Medicare and non-Medicare) for any measure included in a measure topic in a quarter to not be required to submit patient level data for the entire measure topic for that quarter believed that these hospitals should also be exempt from reporting their aggregate population numbers. The commenters believed the administrative burden of determining these numbers for outpatient encounters was so difficult that exempting hospitals due to low volume did little to reduce burden if efforts to prove small numbers were still required and suggested methods for CMS to deem hospitals as small volume, for example, based upon Medicare claims. Some of these commenters suggested the criteria should be number of cases per year rather than number of cases per quarter. Several commenters argued that these hospitals should be exempt from reporting aggregate population figures because hospitals that may never report quality data would still have to establish a mechanism to identify their patient populations every quarter.

Response: We thank these commenters for expressing their concerns regarding burden to small hospitals. As discussed above, for the CY 2010 payment update, we are not requiring the submission of aggregate population figures, either Medicare or non-Medicare, in this final rule with comment period, although hospitals may voluntarily submit such data. We may address this issue in a future rulemaking as hospital outpatient data systems and measure specifications mature and improve.

Comment: One commenter expressed the view that technical limitations of

QualityNet require further evaluation and review. The commenter also recommended that the same processes be used for both the inpatient and outpatient programs rather than creating a separate system and warehouse because the commenter believed that adding a second Web site and different timelines will have negative repercussions for the hospitals.

Response: We have made recent improvements to the infrastructure to process data submitted by hospitals, such as procuring additional bandwidth to accommodate increased data flow. We believe that the processes for the inpatient and outpatient programs are consistent, and the official information source for the two programs is a single Web site: *http://www.qualitynet.org.* There are circumstances that require operational separation of the two programs. It is necessary to have separate data collection tools for the two programs because the two programs are on separate payment cycles with corresponding data cycles. The inpatient hospital payment system operates on a fiscal year basis beginning in October and the outpatient payment system operates on a calendar year basis beginning with January. In addition, due to funding issues under initial implementation, the inpatient and outpatient data systems had to be kept separate. We will consider these comments in the future and thank the commenter for its suggestion for improving processes under the HOP–QDRP.

Comment: Some commenters expressed concerns regarding the differing submission deadlines for HOP–QDRP and RHQDAPU program data. Some commenters objected to what, in their view, was a submission timeline that is 15 days earlier than the current inpatient time line.

Response: It is necessary to separate the data submission schedules to ease the burden on the data warehouse infrastructure, preventing data delays as much as possible. The data collection timeline under initial implementation of the HOP–QDRP was set to allow as much time as possible for hospitals to comply with data reporting requirements for any decisions regarding whether or not a hospital would receive the full CY 2009 payment update. The HOP–QDRP quarterly data reporting deadline of 4 months following the last quarterly discharge date is necessary to provide CMS with more time to process the data and provide hospitals with earlier feedback about their quality measures for improvement work. Based on previous experience with the RHQDAPU program, CMS believes that this timeframe provides hospitals with sufficient time to identify and abstract the data. November 1 is the latest date that we can accept HOP–QDRP data and still compile a list of reporting hospitals to make payment decisions toward the upcoming calendar year payment update; the rest of the reporting schedule follows from this date. For the RHQDAPU program, the quarterly data reporting deadline is 4.5 months after the end of the preceding quarter (the exact dates are posted on the QualityNet Web site). The 4.5 month RHQDAPU program time lag was chosen in order to allow hospitals sufficient time to submit data to The Joint Commission before submitting data to CMS. The majority of hospitals also submit data for many RHQDAPU measures to The Joint Commission, and their data submission deadline is approximately 4 months after the end of the preceding quarter.

After consideration of the public comments received and as discussed in the above responses to those comments, we are adopting as final the proposed data collection and submission requirements with modifications. We are finalizing that hospitals that have five or fewer cases (both Medicare and non-Medicare) for any measure included in a measure topic will not be required to submit patient level data for that entire measure topic for that quarter; however, these hospitals may voluntarily submit these data. We are not requiring the submission of aggregate population figures, Medicare or non-Medicare, for data reported for CY 2009 in order to receive the full CY 2010 payment update, although hospitals may voluntarily submit these data.

3. HOP QDRP Validation Requirements

a. Data Validation Requirements for CY 2010

Validation, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66871), is intended to provide assurance of the accuracy of the hospital abstracted data. A data validation requirement was not implemented for purposes of the CY 2009 annual payment update. In the CY 2009 OPPS/ASC proposed rule (73 FR 41546), we proposed to implement validation requirements that would apply beginning with the CY 2010 payment determinations.

Specifically, we proposed to randomly select, per year, 50 patient episodes of care that a hospital successfully submitted to the OPPS Clinical Warehouse for the relevant time period and validate those data by requesting that the hospital send the supporting medical record documentation that corresponds to each selected episode to a CMS contractor within 30 calendar days of the date of the request. The CMS contractor would then independently reabstract quality measure data elements from those records, compare the reabstracted data to the data originally submitted by the hospital, and provide feedback to each hospital on the results of the reabstraction.

We proposed to validate data reported beginning with January 2009 episodes of care to be used for CY 2010 payment determinations.

Unlike the IPPS RHQDAPU program, where we validate data for each participating hospital each quarter (for a total of 20 cases per year), we proposed to not validate data submitted by every hospital participating in the HOP QDRP every year. Instead, we proposed to validate data from 800 randomly selected hospitals (approximately 20 percent of all participating HOP QDRP hospitals) each year. In other words, only 800 participating HOP QDRP hospitals will have their data validated each year. However, we noted that, because the 800 hospitals will be selected randomly, every HOP QDRP-participating hospital will be eligible each year for validation selection. We believe that the approach of validating a larger number of cases per hospital will produce a more reliable estimate of whether that hospital's data has been submitted accurately and will provide more reliable estimates of measure level data.

For calculation of a hospital's validation score, we proposed that percent agreement for each calculated clinical measure rather than for the individual data elements would be calculated. Due to the contingent nature of data elements comprising quality measures, a mismatch of a few data elements can result in the elimination of subsequent data elements from the data abstraction process. Thus, while the quality measure calculation can match, a low validation score based upon level of data element match can occur. Calculating match rates at the quality measure level obviates the issue of low validation scores at the data element level and also validates the data as they are publicly reported, that is, at the measure level.

To receive the full OPPS payment rate update, we proposed that hospitals must pass our validation requirement of a minimum of 80 percent reliability, based upon our validation process, for the designated time periods. In addition, we proposed that an upper bound of 95

percent confidence interval to measure accuracy would be used.

The methodology we proposed to use for calculating the confidence intervals under the HOP QDRP is the methodology currently utilized for the IPPS RHQDAPU program. We anticipate estimating the percent reliability based upon a review of submitted documentation and then calculating the upper 95 percent confidence limit for that estimate. If that upper limit is above the required 80 percent reliability threshold, we proposed to consider the hospital's data ''validated'' for payment update purposes for CY 2010. We proposed to use the design specific estimate of the variance for the confidence interval calculation, which, in this case, is a single stage cluster sample, with unequal cluster sizes. (For reference, see Cochran, William G. (1977) Sampling Techniques, John Wiley & Sons, New York, chapter 3, section 3.12.) Each sampled medical record is considered as a cluster for variance estimation purposes, as documentation and abstraction errors are believed to be clustered within specific medical records.

We solicited comment on this validation methodology, and stated our belief that this approach is a reliable process that is suitable for the HOP QDRP. We also noted that we are considering whether to propose a similar approach for the RHQDAPU program in future years. We also stated that CMS continues to study approaches to improve its quality data reporting program, and aligning the RHQDAPU program and HOP QDRP validation approaches in the future is one possible area of improvement.

After careful consideration of the following comments received, and as discussed more fully below, we are adopting a voluntary test validation program, the results of which will not affect the CY 2010 payment update for any hospital. Under this program, we intend to conduct a test validation using a random sample of approximately 800 hospitals, sampling 50 or less patient episodes of care per hospital from data submitted to the OPPS Clinical Warehouse for the relevant time period. Participation in the test validation for CY 2010 is voluntary for hospitals, and CMS encourages hospital participation to learn about their data abstraction accuracy.

Comment: Some commenters supported the proposed validation methodology contingent on the incorporation of additional conditions. Some commenters proposed that a test validation be done for each hospital, either for the first year of validation or prior to the first year using a smaller sample, such as 5 patient episodes of care per hospital, and done with sufficient time so that hospitals could learn from any mistakes. One commenter suggested that this ''test'' validation be done using second quarter 2008 data. Other commenters recommended that the first validation done be considered a ''test run,'' tying validation to payment determinations in CY 2011.

Response: We thank the commenters for these suggestions. We acknowledge the need for hospitals to gain experience with any validation process for HOP QDRP data collection. After consideration of the public comments received, we are adopting a voluntary test validation program, the results of which will not affect the CY 2010 payment update for any hospital. Under this program, we intend to conduct a test validation using a random sample of approximately 800 hospitals, sampling 50 or less patient episodes of care per hospital from data submitted to the OPPS Clinical Warehouse for the relevant time period. We intend to utilize data beginning with January 1, 2009 patient episodes of care. We will validate those data by requesting that the hospital voluntarily send the supporting medical record documentation that corresponds to each selected episode-of-care to a CMS contractor within 30 calendar days of the date of the request. The CMS contractor will independently reabstract quality measure data elements from those records, compare the reabstracted data to the data originally submitted by the hospital and provide feedback to each sampled hospital on the results of the reabstraction. We will utilize a measure match approach. We intend to calculate confidence intervals for data validated for feedback purposed, but will not require the passing of any validation threshold for purposes of the CY 2010 update. We intend to provide additional feedback to all hospitals participating in the HOP QDRP in a manner that does not identify individual hospitals or hospital information in any way. Hospitals are encouraged to participate in any validation efforts undertaken so that the information gleaned can be used toward improving their and other hospitals' data abstraction and collection processes. We plan to propose a validation program for the CY 2011 payment update in our CY 2010 OPPS/ASC proposed rule.

Comment: Many commenters supported the proposed validation process and agreed with the approach of validating the measure rates rather than the data element rate. The commenters cited various reasons for supporting the proposed validation process, stating that it was a reasonable approach to ensure accuracy, would provide a more accurate picture of performance, and was an improvement of the inpatient validation process. One commenter agreed with the proposed validation approach using a sample of hospitals as long as lessons learned are shared with hospitals in a timely manner. Some commenters expressed appreciation for providing time for hospitals to implement quality measures and work on their performance data before validation and public reporting occur.

Some commenters requested more detail with regard to the selection process for the sampled hospitals, the notification process, or the actual validation process. Some commenters urged that the selection process be totally random and unbiased. Another commenter stated that hospitals should also continue to validate their own data for overall accuracy and for abstractor accuracy because the integrity of the data is critical. Several commenters recommended that the timeframe to provide the information for validation be established as 60 days rather than 30 days to allow additional time to retrieve, duplicate, and submit records. A few commenters believed that hospitals selected for validation in one year be excluded from the validation pool for some specified time, for example, 1 to 2 years, or should be selected no more than twice in 5 years based upon a criteria, such as there being no identified errors or passing at the 80-percent level with those not meeting the criteria being subject to potential selection again the following year. One commenter believed that, for there to be no bias in the selection methodology, statistically speaking, a hospital should not be selected 2 years in a row. Some commenters asked that CMS indicate how the proposed validation approach would be applied for measures calculated from claims data. Many commenters recommended using a similar validation approach for the RHDQAPU program. Some commenters recommended that the proposed HOP QDRP approach be used for all Medicare quality measure data reporting programs, including the PQRI.

One commenter did not agree with validation of a larger number of cases, though all hospitals are eligible. The commenter was concerned that if not all hospitals are validated on a regular basis, this could lead to lower standards, that 50 charts would unduly burden smaller hospitals, and supported the first alternative approach for

validation requiring 20 charts per year for each hospital. Commenters expressed concerns about current factors that could adversely affect validation. One concern was that CPT and E&M codes were being required to be part of documentation required for submission for validation. Another concern was that the criteria for inclusion do not take into account cancelled procedures, which the commenters indicated was an issue because HOP QDRP abstraction does not allow for the collection of CPT coding modifiers, resulting in these records failing the measure criteria. Some commenters expressed concern that hospitals risk the potential to appear worse at the quality measure related to prophylactic antibiotic prior to incision than actually exists and would lose their full payment update. Commenters expressed concerns regarding the 80-percent reliability threshold from chart validation. Some commenters stated that the 80 percent threshold was too stringent, urging a lower level set. Some of these commenters stated that statistical analysis of collected data should be done to assess if 80 percent is an objective number for passing the validation process. Other commenters asked that CMS include more information about the methodology and how it would be applied in this final rule with comment period.

Response: We thank those commenters that supported our proposed validation method. As discussed above, we are implementing a voluntary test validation program in CY 2009, the results of which will not affect the CY 2010 payment update for any hospital. We will consider all of the commenters' suggestions and concerns when we propose a HOP QDRP validation program for the CY 2011 payment update in our CY 2010 OPPS/ASC proposed rule and when we propose RHQDAPU program validation requirements in the FY 2010 IPPS proposed rule.

After consideration of the public comments received and as discussed above, we are not finalizing the proposed validation method to be used toward CY 2010 payment decisions. We acknowledge the need for hospitals to gain experience with any validation process for HOP QDRP data collection. In light of the public comments received, we are voluntary test validation program in CY 2009, the results of which will not affect the CY 2010 payment update for any hospital. Under this program, we intend to conduct a test validation using a sample of approximately 800 hospitals, sampling 50 or less patient episodes of care per hospital from data submitted to the OPPS Clinical Warehouse for the relevant time period. We intend to utilize data beginning with January 1, 2009 patient episodes of care. We will validate those data by requesting that the hospital voluntarily send the supporting medical record documentation that corresponds to each selected episode-of-care to a CMS contractor within 30 calendar days of the date of the request. The CMS contractor will independently reabstract quality measure data elements from those records, compare the reabstracted data to the data originally submitted by the hospital and provide feedback to each sampled hospital on the results of the reabstraction. We will utilize a measure match approach. We will not require the passing of any validation threshold for purposes of the CY 2010 update, but will calculate these values as part of feedback supplied to hospitals which participate in validation efforts. We intend to provide feedback to all hospitals participating in the HOP QDRP in a manner that does not identify individual hospitals or hospital information in any way. Hospitals are encouraged to participate in any validation efforts undertaken so that the information gleaned can be used toward improving their and other hospitals' data abstraction and collection processes. We plan to propose a validation program for the CY 2011 payment update in our CY 2010 OPPS/ASC proposed rule.

b. Alternative Data Validation Approaches for CY 2011

In the CY 2009 OPPS/ASC proposed rule (73 FR 41546), we also solicited comments on three alternative validation methodologies. We are considering whether we could apply one of these methodologies to validate data as part of our CY 2011 payment determination. The first alternative approach would be to validate data from all participating HOP QDRP hospitals, as is currently done under the RHQDAPU program. Under this approach, data validation would be done on a random sample of 5 records per quarter (20 records per year) per hospital.

A second alternative approach would be to select targeted hospitals based on criteria designed to measure whether the data being reported by them raises a concern regarding their accuracy. We welcomed suggestions for criteria to be used for targeting hospitals for validation. Either percent agreement at the clinical measure level or the data element level (currently used for the RHQDAPU program) could be calculated for the validation score. Because few data have been collected under the HOP QDRP at this point, we are considering this approach for possible use in future years.

A third alternative approach would involve some combination of the two approaches discussed above.

Comment: Many commenters disagreed with validating data from all participating HOP QDRP hospitals following the process currently used under the RHQDAPU program. The commenters stated that a measure match rate approach as proposed was preferable.

Response: We thank the commenters for expressing their views.

Comment: Some commenters supported the second and third alternative methods proposed as also effective approaches for data validation and suggested criteria for targeting. In support of the third alternative method, commenters stated that this would be an efficient use of both hospital and CMS resources and would assure that all participating HOP QDRP hospital data are valid. Other commenters expressed opposition to use of criteria to target hospitals for validation or the inability to comment due to lack of detail.

Response: We thank these commenters for their views on the use of criteria for targeting hospitals for validation purposes. As we stated, these additional validation approaches were for consideration in future years and that we did not yet have criteria for targeting. We will consider the suggested criteria in future validation planning in future rulemaking. As discussed in section 3(a) of the HOP–QDRP portion of this final rule, we will be conducting a test validation program this year and the results of the validation will not affect the CY 2010 annual payment update.

Comment: One commenter stated that some vendors provide data validation services to hospitals and suggested that CMS entertain a formal relationship with such entities rather than being solely responsible for national data validation.

Response: We thank the commenter for this information.

We appreciate all the public comments received regarding the alternate validation approaches proposed and will take them into account as we develop validation proposals for CY 2011.

F. Publication of HOP QDRP Data

Section 1833(t)(17)(E) of the Act requires that the Secretary establish procedures to make data collected under this program available to the public and

to report quality measures of process, structure, outcome, patients' perspectives of care, efficiency, and costs of care that relate to services furnished in outpatient settings in hospitals on the CMS Web site. We intend to make the information collected under the HOP QDRP public in CY 2010 by posting it on the CMS Web site. Participating hospitals will be granted the opportunity to review this information as we have recorded it before the information is published.

CMS requires hospitals to sign and submit a Notice of Participation form in order to participate in the HOP QDRP. Hospitals signing this form agree that they will allow CMS to publicly report the quality measures as required by the HOP QDRP.

All hospitals have a unique CCN, whereas a single hospital may have multiple National Provider Identifiers (NPI), another CMS identifier. In the CY 2009 OPPS/ASC proposed rule, we proposed for CY 2010 that hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes (73 FR 41546). We also proposed to publish quality data by CCN under the HOP QDRP; however, we will note on our Web site where the publicly reported measures combine results from two or more hospitals. This approach is consistent with the approach taken under the IPPS RHQDAPU program.

Comment: Several commenters agreed with the proposal that hospitals with the same CCN have their data publicly reported as one facility (with a notation when data from more than one hospital is combined). Some of these commenters supported the proposal that they believed that the proposal would add important alignment of clinical reporting with financial reporting.

Response: We thank the commenters for their support of our proposal to report data by CCN. We proposed to report data by CCN for several reasons. First, the unit affected by the OPPS annual payment update subject to meeting the requirements under the HOP QDRP is handled by CCN; it is not separated by NPI or other individual facility identifier. Second, hospitals meet survey and certification requirements by CCN, again not by any other individual facility identifier. Third, the additional Medicare identifier for facilities, the NPI, is not a uniform identifier; the NPI can refer to, for example, an individual clinic, a provider group, or a hospital. Fourth, as stated by several commenters, reporting by CCN would align the reporting of quality of care data with financial data. For these reasons, at this time, we consider the CCN as the payment and hospital certification identifier representative of entire hospital entity to be the appropriate identifier for public reporting.

Comment: A few commenters urged CMS to identify a means to report each facility's performance in order to provide accurate information to consumers trying to assess the quality of a given hospital.

Response: For reasons discussed above, we believe that the CCN is currently the most appropriate identifier for public reporting. However, we are aware that this aspect of shared CCNs is a serious and complex problem and we are continuing to work toward a resolution of the problem that accommodates both consumer and hospital payment needs. We understand that there is not always a one-to-one relationship between the NPI and the CCN upon which the HOP QDRP is based. At this time, we are trying to assess the extent of this problem. In terms of determining eligibility of an HOPD's full annual payment update, we have addressed this by maintaining an NPI to CCN crosswalk. For CY 2010 public reporting, data would be publicly reported on the CMS Web site by CCN, but we intend to indicate instances where data from two or more hospitals are combined.

Comment: Numerous commenters expressed support for public reporting of the hospital outpatient measures, and recommended that the hospital outpatient measures be added to the existing Hospital Compare tool. The commenters also recommended evaluation of the HOP QDRP data and consumer testing before any information is released publicly to ensure that information provided to consumers and physicians is not misleading. One commenter expressed concern over the possibility of less than 12 months of data being used for public reporting, and recommended that all measures have a minimum of 12 months implementation before they are eligible for inclusion in public reporting and the validation process affecting hospitals' annual payment updates.

Response: We will consider using Hospital Compare for the public reporting of HOPD data. However, no decision has been made at this time. As part of our measure maintenance contract, we continue to evaluate the measure specifications and measures data. We conduct consumer testing on a regular basis to inform decisions about Web site display, language and navigation. We will implement public reporting for outpatient measures in CY 2010, but have not made any decisions about what quarters will be reported when they are reported. In the case of our other public reporting timeframes, data reported in March 2010 are to be based upon 3Q08 through 2Q09, and data reported in December 2010 are to be based upon 2Q09 through 1Q10. However, we may also choose to report less than a full 12 months when we begin public reporting under HOP QDRP.

Comment: One commenter believed that, for providers and consumers, the information presented on Hospital Compare is confusing, and it is difficult to decipher which information is representative of the total population or only the Medicare population. The commenter stated that Medicare claims-based information under the HOP QDRP will continue to add to the confusion of what is representative of the total population served by the hospital versus which is only representative of the Medicare population.

Response: We understand that this is a problem and would prefer to have data that represent the entire population, that is, all-payer, for all measures. Unfortunately, this is not possible at this time. We have access only to Medicare administrative (claims and enrollment) data that are used for the outcome measures (30-day risk-standardized mortality and newly adopted readmission rates) reported on Hospital Compare. We are interested in obtaining all-payer administrative data, but there are infrastructure and other challenges. Until we have access to all-payer administrative data, we make every effort to label the data sources on Hospital Compare so that users understand that the underlying populations differ for some measures.

After consideration of the public comments received and as noted in the above responses, in this rule with comment period, we are finalizing our proposal that hospitals sharing the same CCN must combine data collection and submission across their multiple campuses for all HOP QDRP measures. We also are finalizing our proposal to publicly report HOP QDRP measures by CCN with notation on the Web site where the publicly reported measures combine results from two or more hospitals. Participating hospitals will be granted the opportunity to review this information as we have recorded it before the information is published. We intend to publicly report on our Web site hospital outpatient measures data in CY 2010 but have not made a decision regarding what quarters will be reported or when these data will be reported. In addition, we will continue to explore

the use of Hospital Compare and other locations for the public reporting of HOPD data. We anticipate communicating our decision about these reporting issues in the CY 2010 OPPS/ASC proposed rule.

G. HOP QDRP Reconsideration and Appeals Procedures

When the IPPS RHQDAPU program was initially implemented, it did not include a reconsideration submission 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 IPPS RHQDAPU program. In the CY 2009 OPPS/ASC proposed rule (73 FR 41547), we proposed a mandatory reconsideration and appeals process that would apply to the CY 2010 payment decisions. Under our proposal, in order to receive reconsideration of a CY 2010 payment decision, the hospitals must—

(1) Submit to CMS, via QualityNet, a Reconsideration Request form that will be made available on the QualityNet Web site. This form shall contain the following information:

- Hospital Medicare ID number known as the 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 must identify the hospital's specific reason(s) for believing it met the HOP QDRP program requirements and should receive a full annual payment update.
- CEO 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 material that the hospital submitted to CMS in order to receive the full payment update for the year that is the subject of the reconsideration request. Such material would include, but not be limited to, the applicable Notice of Participation form, quality measure data that the hospital submitted, and data that the hospital submitted in response to a validation request.
- QualityNet System Administrator contact information, including name, e-mail address, telephone number, and mailing address (must include physical address, not just the post office box).
- The request must be signed by the hospital's CEO.

(2) Following receipt of a request for reconsideration, CMS will—

- Provide an e-mail acknowledgement, using the contact information provided in the reconsideration request, to the CEO and the QualityNet Administrator notifying them that the hospital's request has been received.
- Provide a formal response to the hospital CEO, using the contact information provided in the reconsideration request, notifying the hospital of the outcome of the reconsideration process.

If a hospital is dissatisfied with the result of a HOP QDRP reconsideration decision, the hospital may file a claim under 42 CFR Part 405, Subpart R (PRRB appeal).

Comment: Several commenters supported hospital appeals and reconsideration processes and urged CMS to have these processes in place at the same time as the validation process and that strict timelines be defined so that the public has access to information as quickly as possible.

Response: We thank these commenters for their support of hospital appeals and reconsideration processes. We plan to complete any CY 2009 reconsideration reviews and communicate the results of these determinations within 60 to 90 days following the date of the request for reconsideration. If a hospital is dissatisfied with the result of this reconsideration, the hospital may file a claim under the PRRB process with its associated timelines. As discussed previously, we will be conducting a voluntary test validation program using data from services beginning January 1, 2009; there is no validation requirement to be met to be considered toward payment decisions affecting CY 2010 payment. The results of this test validation program will not affect the CY 2010 payment update for any hospital.

Comment: One commenter stated that the PRRB process under the RHQDAPU program upon which the proposed reconsideration and appeals process for the HOP QDRP is modeled has been unduly long and hospitals do not learn of CMS' decision on reconsideration requests in a timely manner. The commenter urged CMS to revise the process to produce more timely decisions. Another commenter recommended that an appeal process be at least 90 days due to the time involved to investigate and respond.

Response: We interpret the comment to refer to the proposed HOP–QDRP reconsideration process. We believe that there are competing interests of timeliness and completeness in any reconsideration and appeals process. We agree that hospitals need to know the results of any reconsideration and appeals process as quickly as possible. As stated above, we plan to complete the reconsideration process within 60 to 90 days following the date of the request for reconsideration. Based on previous experience with the RHQDAPU reconsideration process, we believe that this timeframe is necessary to adequately review the estimated volume of HOP–QDRP reconsideration cases. If a hospital is dissatisfied with the result of this reconsideration, the hospital may file a claim under the PRRB process, with its associated timelines (see 42 CFR Part 405, Subpart R (PRRB appeal)).

After consideration of the public comments received, we are adopting as final the HOP QDRP reconsideration and appeals process as proposed. We believe that any CY 2009 reconsideration review will require 60 to 90 days for completion based upon experience with the RHQDAPU program and we plan to communicate all determinations within 60 to 90 days following the request for reconsideration.

H. 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 sections 1833(i)(2)(D)(iv) and1833(i)(7) to the Act. 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. These provisions permit, but do not require, the Secretary to require ASCs to submit such data and to reduce any annual increase for noncompliant ASCs.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66875), we indicated that we intended to implement the provisions of section 109(b) of the MIEA–TRHCA in a future rulemaking. While we 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, we believed that the transition to the revised payment system in CY 2008 posed such a significant challenge to ASCs that it would be most

appropriate to allow some experience with the revised payment system before introducing other new requirements. We believed that implementation of quality reporting in CY 2008 would require systems changes and other accommodations by ASCs, facilities which do not have prior experience with quality reporting as hospitals already have for inpatient quality measures, at a time when they are implementing a significantly revised payment system. We believed that our CY 2008 decision to implement quality reporting for HOPDs prior to establishing quality reporting for ASCs would allow time for ASCs to adjust to the changes in payment and case-mix that are anticipated under the revised payment system. We would also 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 in ASCs.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41547), we noted that 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 2009 and, therefore, we intend to implement the provisions of section 109(b) of the MIEA–TRHCA in a future rulemaking. We invited public comment on this deferral of quality data reporting for ASCs and invited suggestions for quality measures geared toward the services provided by ASCs. We also sought comment on potential reporting mechanisms for ASC quality data, including electronic submission of these data.

Comment: Many commenters agreed with the CMS proposal to defer quality data reporting from ASCs until a later rulemaking. Some of the commenters agreed with CMS' assessment regarding the need to complete implementation of the revised ASC payment system before implementing quality measure data reporting.

Response: We thank these commenters for their support of our decision to defer quality data reporting from ASCs until a later rulemaking.

Comment: One commenter disagreed with CMS' assessment regarding the revised ASC payment system posing ongoing challenges to such a magnitude as to prevent the reporting of quality of care data in 2009.

Response: We thank the commenter for this view, but we still believe that we should not increase burdens on ASCs at this time with a new data reporting system while implementing a revised payment system.

Comment: Several commenters supported measuring the quality of services provided in the ASC setting. Some commenters urged the implementation of a quality reporting system for ASCs as soon as possible. Some commenters stated that such reporting with similar measures would allow the same level of transparency for both hospitals and ASCs. Some commenters suggested that reporting begin in CY 2009 on the five NQF-endorsed quality measures that were developed by the ASC Quality Collaboration. Some commenters stated that selected measures should include an electronic data submission mechanism. Several commenters expressed concerns of the potential data collection burden for ASCs; some of these commenters suggested the administrative claims approach to be the most feasible for ASCs to submit quality of care data. One commenter recommended that ASCs not be required to report the same quality data as that as HOPDs due to the nature of their services.

Response: We will consider these comments and suggestions for future implementation of ASC quality measure data.

Comment: One commenter suggested that a mandatory reconsideration and appeals process provided that data under reconsideration or appeal not be publicly displayed until resolution of such reconsideration or appeal for ASC reporting and that an appropriate method of applying the required reduction to payments for ASCs that do not meet requirements be devised.

Response: We have not proposed any reconsideration and appeals process for ASC quality measure reporting. However, we appreciate these comments and suggestions for future implementation of a reconsideration and appeals process for ASC quality measure data reporting and will consider them for future implementation.

After consideration of the public comments received, we continue to believe that promoting high quality care in the ASC setting through quality reporting is highly desirable and is fully in line with our efforts under other payment systems. We intend to implement quality measures in the ASC setting in a future rulemaking.

I. FY 2010 IPPS Quality Measures Under the RHQDAPU Program

In the FY 2009 IPPS proposed rule (73 FR 23651), we noted that, to the extent that the proposed quality measures for FY 2010 under the RHQDAPU program had not already been endorsed by a consensus building entity such as the NQF, we anticipated that they would be endorsed prior to the time that we issued the FY 2009 IPPS final rule. We stated that we intended to finalize the FY 2010 RHQDAPU program measure set for the FY 2010 payment determination in the FY 2009 IPPS final rule, contingent upon the endorsement status of the proposed measures. However, we stated that, if a measure had not received NQF endorsement by the time we issued the FY 2009 IPPS final rule, we intended to finalize that measure for the RHQDAPU program measure set in this CY 2009 OPPS/ASC final rule with comment period if the measure received endorsement prior to the time we issued this CY 2009 OPPS/ASC final rule with comment period (73 FR 23651). We previously have finalized some measures in this manner when endorsement of a measure is expected by the publication date of an upcoming rule (72 FR 66876). We requested public comment on these measures in the FY 2009 IPPS proposed rule and received comments on these measures during the FY 2009 IPPS proposed rule public comment period. We responded to these comments in the FY 2009 IPPS final rule (73 FR 48606).

In the FY 2009 IPPS final rule (73 FR 48611), we set out, as listed below, two measures which had not yet received NQF endorsement, and stated that we intended to adopt for the FY 2010 RHQDAPU program measure set in this CY 2009 OPPS/ASC final rule with comment period if the measures receive endorsement from a national consensus-based entity such as NQF:

PROPOSED QUALITY MEASURES TO BE FINALIZED IN THE CY 2009 OPPS/ASC FINAL RULE WITH COMMENT PERIOD

[Contingent on endorsement by national consensus-building entity]

Readmission Measures (Medicare Patients)
- AMI 30–Day Risk Standardized Readmission Measure (Medicare patients).
- Pneumonia (PN) 30–Day Risk Standardized Readmission Measure (Medicare patients).

NQF has endorsed the two measures listed above and we are finalizing the Risk-Standardized Readmission measures (Medicare patients) for AMI and Pneumonia to be included in the CY 2010 RHQDAPU program measure set.

XVII. Healthcare-Associated Conditions

A. Background

As noted in its landmark 1999 report ''To Err is Human: Building a Safer Health System,'' the Institute of Medicine found that medical errors are a leading cause of morbidity and mortality in the United States. Total national costs of these errors due to lost productivity, disability, and health care costs were estimated at $17 billion to $29 billion.[2] As one approach to combating healthcare-associated conditions, in 2005, Congress authorized CMS to adjust Medicare IPPS hospital payments to encourage the prevention of these conditions. Section 1886(d)(4)(D) of the Act (as added by section 5001(c) of the Deficit Reduction Act (DRA) of 2005, Public Law 109–171) required the Secretary to select by October 1, 2007, at least two conditions that are: (1) High cost, high volume, or both; (2) assigned to a higher paying DRG when present as a secondary diagnosis; and (3) could reasonably have been prevented through the application of evidence-based guidelines. CMS has titled this initiative Hospital-Acquired Conditions (HAC) and Present on Admission (POA) Indicator Reporting. Beginning October 1, 2008, Medicare cannot assign an inpatient discharge that includes only the selected conditions to a higher-paying MS–DRG unless these conditions were present on admission. Beginning October 1, 2007, CMS required hospitals to begin submitting information on Medicare inpatient hospital claims specifying whether diagnoses were present on admission. Through FY 2008 and FY 2009 IPPS rulemaking, CMS selected 10 categories of hospital-acquired conditions (72 FR 47202 through 47218 and 73 FR 23547 through 23562).

The preventable hospital-acquired conditions payment provision at section 1886(d)(4)(D) of the Act is part of an array of Medicare value-based purchasing (VBP) tools that CMS is using to promote increased quality and efficiency of care. These tools include measuring performance, using payment incentives, publicly reporting performance results, applying national and local coverage policy decisions, enforcing conditions of participation, and providing direct support for providers through QIO activities. CMS' application of VBP tools through various initiatives is transforming Medicare from a passive payer to an active purchaser of higher-value health care services. CMS is applying these strategies across the continuum of care for Medicare beneficiaries.

B. Expanding the Principles of the IPPS Hospital-Acquired Conditions Payment Provision to the OPPS

As discussed in the CY 2009 OPPS/ASC proposed rule (73 FR 741548), the principle of Medicare not paying more for the preventable hospital-acquired conditions during inpatient stays paid under the IPPS could be applied more broadly to other Medicare payment systems for conditions that occur or result from health care delivered in other settings. Other potential settings of care include HOPDs, ASCs, SNFs, home health care, end-stage renal disease (ESRD) facilities, and physician practices; therefore, we will refer to conditions that occur in settings other than the inpatient hospital setting as ''healthcare-associated conditions'' and continue to refer to those that occur in the inpatient setting as ''hospital-acquired conditions.'' Implementation of this concept would be different for each setting, as each Medicare payment system is different. In addition, selected conditions must be reasonably preventable through the application of evidence-based guidelines and this might vary for candidate conditions across the various care settings. However, CMS is committed to aligning incentives across settings of care for all of CMS' VBP initiatives, including the hospital-acquired conditions payment provision.

The risks of preventable medical errors leading to the occurrence of healthcare-associated conditions are likely to be high in the outpatient setting, given the large number of encounters and exposures that occur in these settings. Approximately 530,000 preventable drug-related injuries are estimated to occur each year among Medicare beneficiaries in outpatient clinics.[3] These statistics clearly point to the significant magnitude of the problem of healthcare-associated conditions in outpatient settings. Recent trends have shown a shift in services from the inpatient setting to the HOPD, and we expect the occurrence of healthcare-associated conditions stemming from outpatient care to grow directly as a result of this shift in sites of service.

For these reasons, we believe the HOPD, where a broad array of services covered and paid under the OPPS are provided, could be another setting for Medicare to extend the concept of not paying more for preventable healthcare-associated conditions that occur as a result of care provided during an encounter. Hospitals provide a range of services under the OPPS that may overlap or precede the inpatient activities of the hospital, including many surgical procedures and diagnostic tests that are commonly performed on both hospital inpatients and outpatients. Similarly, individuals who are eventually admitted as hospital inpatients often initiate their hospital encounter in the HOPD, where they receive clinic or emergency department visits or observation care that precede their inpatient hospital admission. In addition, like the IPPS, the OPPS is also subject to the ''pay-for-reporting'' provision that affects the hospital annual payment update, by the authority of section 1833(t)(17) of the Act (as amended by section 109(a) of the MIEA–TRHCA). Under this authority, hospitals report quality data for specified performance measures related to hospital outpatient services under the HOP QDRP. Hospitals that fail to meet the reporting requirements established by CMS for the payment update year receive a reduced payment update that

[2] Institute of Medicine: To Err Is Human: Building a Safer Health System, November 1999. Available at: *http://www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf.*

[3] Asplen, P., Wolcott, J., Bootman, J.L., Cronenwett, L.R. (editors): Preventing Medication Errors: Quality Chasm Series, The National Academy Press, 2007. Available at: *http://www.nap.edu/catalog.php?record_id=11623.*

is applicable to OPPS payments for most services furnished by hospitals in outpatient settings in the succeeding year. The HOP QDRP is further discussed in section XVI. of this final rule with comment period.

As noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41548), we did not propose new Medicare policy in this discussion of healthcare-associated conditions as they relate to the OPPS. Instead, we solicited public comments on options and considerations, including statutory authority, related to extending the IPPS hospital-acquired conditions payment provision for hospitals to the OPPS. As indicated in the proposed rule, we understand that there would be challenges in expanding the IPPS provision to other settings paid under different Medicare payment systems, and we specifically invited public comments that present ideas and models for extending the principle behind the IPPS provision to the OPPS. To stimulate reflection and creativity, we presented discussion in the following areas:

- Criteria for possible candidate OPPS conditions
- Collaboration process
- Potential OPPS healthcare-associated conditions
- OPPS infrastructure and payment for encounters resulting in healthcare-associated conditions

1. Criteria for Possible Candidate OPPS Conditions

We have applied the following statutory criteria to the analysis of candidate inpatient conditions for the IPPS hospital-acquired conditions payment provision:

- Cost or Volume—Medicare data must support that the selected inpatient conditions are high cost, high volume, or both.
- Complicating Conditions (CC) or Major Complication Conditions (MCC)—Selected inpatient conditions must be represented by ICD–9–CM diagnosis codes that clearly identify the condition, are designated as a CC or an MCC, and result in the assignment of the case to an MS–DRG that has a higher payment when the code is reported as a secondary diagnosis. That is, selected inpatient conditions must be a CC or an MCC that would, in the absence of this provision, result in assignment to a higher paying MS–DRG.
- Evidence-Based Guidelines—Selected inpatient conditions must be reasonably preventable through the application of evidence-based guidelines. By reviewing guidelines developed by professional organizations, academic institutions, and other entities such as the Healthcare Infection Control Practices Advisory Committee (HICPAC), we evaluated whether guidelines are available that hospitals should follow to prevent the condition from occurring in the hospital.
- Reasonably Preventable—Selected inpatient conditions must be reasonably preventable through the application of evidence-based guidelines.

In the CY 2009 OPPS/ASC proposed rule (73 FR 41549), we specifically sought public comment on the applicability of these criteria to the selection of candidate healthcare-associated conditions for the OPPS. We indicated in the proposed rule that we were specifically interested in public comment on the reasonably preventable criterion in the HOPD setting. As we explained in that rule, there are significant infrastructure differences between the IPPS and the OPPS, as discussed further in section XVII.B.4. of this final rule with comment period. Thus, in the proposed rule, we expressed interest in receiving public comments generally and specifically those that would help answer the following questions:

- Are there examples within the context of the reporting of ICD–9–CM codes for diagnoses and HCPCS codes for services on OPPS claims that could be used to identify where a higher payment for a hospital outpatient encounter would result from a healthcare-associated condition?
- Are there examples of evidence-based guidelines related to the prevention of high volume or high cost conditions, or both, that are sufficiently rigorous to permit selection of healthcare-associated conditions that could reasonably have been prevented in the HOPD setting?
- What other criteria should be considered in the selection of healthcare-associated conditions for the OPPS?

2. Collaboration Process

CMS has worked with public health and infectious disease experts from the Centers for Disease Control and Prevention (CDC) to select hospital-acquired conditions, including infections, that meet the statutory criteria under section 1886(d)(4)(D) of the Act for application in the hospital inpatient setting. CMS and CDC have also collaborated to develop the process for submission of a present on admission (POA) indicator on the inpatient claim for each diagnosis. We would expect to continue our collaboration with CDC to examine the relevance and applicability of a POA indicator in the HOPD setting, and also to utilize its expertise in chronic diseases in the selection of candidate healthcare-associated conditions for the OPPS. In addition, we would expect to seek collaboration with the Agency for Healthcare Research and Quality (AHRQ) to utilize its expertise in patient safety. We would also expect to seek collaboration with other Federal agencies and with medical specialty societies. In the CY 2009 OPPS/ASC proposed rule, we specifically solicited public comment regarding a collaborative process for the identification of candidate healthcare-associated conditions for hospital outpatient services and a mechanism for public input from stakeholders.

3. Potential OPPS Healthcare-Associated Conditions

The FY 2008 IPPS final rule (72 FR 47202 through 47218) and the FY 2009 IPPS final rule with comment period (73 FR 48471 through 48491) provided a detailed analysis supporting the selection of the hospital-acquired conditions. In the CY 2009 OPPS/ASC proposed rule (73 FR 41550), we solicited public comments on the following conditions that have been selected as inpatient hospital-acquired conditions:

- Object left in during surgery;
- Air embolism;
- Blood incompatibility; and
- Falls and trauma fractures, dislocations, intracranial injuries, crushing injuries, and burns.

We observed that the characteristics of these conditions are such that they would be relatively straightforward to incorporate in an OPPS healthcare-associated conditions payment provision. For example, these events would likely occur and be coded in the timeframe of an OPPS encounter reported on a single claim and determination of the occurrence of these events would probably not require sequential evaluation of claims over time. We specifically requested public comment on the potential for considering these conditions as healthcare-associated conditions for the HOPD.

We acknowledged that reporting even this short list of healthcare-associated conditions as a secondary diagnosis on a claim in order to attribute their occurrence to the HOPD encounter might present problems for hospitals, particularly for the conditions resulting from falls or trauma. Thus, we specifically requested public comment on whether or not we could assume that these conditions reported as secondary diagnoses on OPPS claims would have

developed during the encounter or whether the reporting of POA indicator information should be required under the OPPS (and perhaps under every Medicare payment system) because POA data increase the utility of claims for analyzing the characteristics of a clinical encounter. More generally, we explained that we recognize that patients may be cared for by different providers across settings and that the provider caring for certain types of complicating conditions may not have provided the healthcare services that led to the healthcare-associated condition. Therefore, we indicated in the CY 2009 OPPS/ASC proposed rule (73 FR 41550) that we welcomed broad public comment on the approaches and challenges related to the appropriate attribution of different types of healthcare-associated conditions encountered in the HOPD. Moreover, we also understand that patients differ in their severity and complexity of disease, as well as their likelihood of following medical recommendations. Therefore, we specifically requested public comment on how to account for patient-specific risk factors that would increase the likelihood of the occurrence of healthcare-associated conditions (73 FR 41550).

Ultimately, payment policy for healthcare-associated conditions under the OPPS should fully address the broad range of clinical services in the HOPD where preventable healthcare-associated conditions may harm Medicare beneficiaries. Therefore, we solicited public comment on additional candidate conditions that could have applicability to the OPPS, beyond those mentioned above that would be extensions from the IPPS final or proposed hospital-acquired conditions. We indicated that we were particularly interested in recommendations of preventable healthcare-associated conditions that are likely to occur with frequency in the HOPD (and other outpatient settings) and that may be associated with significant harm, such as adverse drug events related to medication errors or other complications of care for which we either currently have no diagnosis codes or where correct coding for such occurrences has not been clearly defined.

External Cause-of-Injury coding (E-coding) may represent a mechanism for coding clarity for preventable healthcare-associated conditions such as adverse drug events related to medication errors. The CDC has been interested in further developing and expanding strategies to improve E-coding. A recent CDC Workgroup report discussed the importance and value of using high-quality E-coding.[4] Workgroup recommendations included enhancing the completeness and accuracy of E-coding and making E-coded data more useful for injury surveillance and prevention activities (including medical errors) at the local, State, and Federal levels.

4. OPPS Infrastructure and Payment for Encounters Resulting in Healthcare-Associated Conditions

The OPPS infrastructure is a prospective payment system based on relative costs from hospital claims for services assigned to APC groups, where there is an individual payment rate that is specific to each APC. Each APC contains HCPCS codes for items or services that are clinically similar and that have comparable resource costs. In most cases, an APC payment is made for each unit of each separately payable HCPCS code through the code's assigned APC. For a single hospital outpatient clinical encounter in which a patient receives services described by several HCPCS codes with individual APC assignments (for example, emergency department visit, first hour of therapeutic intravenous infusion, chest x-ray, and electrocardiogram), the hospital would receive multiple APC payments for that encounter. This payment approach is altogether different from the MS–DRG-based IPPS, which groups the services provided to an inpatient into an assigned MS–DRG for which a single payment for the inpatient case is made. Under the MS–DRGs that took effect in FY 2008, there are currently 258 sets of MS–DRGs that can split into 2 or 3 subgroups based on the presence or absence of a CC or an MCC. (We refer readers to the FY 2008 IPPS final rule with comment period for a discussion of DRG reforms (72 FR 47141).) Prior to the October 1, 2008 effective date of the IPPS hospital-acquired conditions payment provision, if a condition acquired during a hospital stay was one of the conditions on the CC or MCC list, the hospital received a higher payment under the MS–DRGs. Beginning October 1, 2008, Medicare can no longer assign an inpatient hospital discharge to a higher paying MS–DRG if a selected hospital-acquired condition was not present on admission and if no other CC or MCC is present. That is, the case will be paid as though the secondary diagnosis (selected hospital-acquired condition) was not present, unless a nonselected secondary diagnosis that is a CC or an MCC is also present. Medicare will continue to assign a discharge to a higher paying MS–DRG if the selected condition was present on admission.

As discussed previously, the OPPS currently has neither the infrastructure to identify POA indicator data nor the ability to stratify by CC or MCC for differential payment under the present APC payment methodology. OPPS claims report an ''admitting diagnosis'' that identifies the reason for the encounter prior to the establishment of the principal diagnosis, but the admitting diagnosis cannot be presumed to be equivalent to a diagnosis that is present on admission as reported on an inpatient claim. As a consequence, initial application of a healthcare-associated conditions payment policy under the OPPS might be limited in its scope of conditions as discussed above and in its options for payment adjustment. We specifically requested public comment on how necessary a POA indicator would be for the candidate conditions we had identified for potential use in the OPPS setting, and on how the OPPS infrastructure could be modified to allow for the incorporation of any POA information (73 FR 41550 through 41551).

Further, we also solicited recommendations on how hospital payment for a clinical encounter in the hospital outpatient setting (which could include multiple individual APC payments) could be adjusted to reflect a derivative payment reduction similar to the CC/MCC MS–DRG adjustment for hospital-acquired conditions under the IPPS. Without a POA and risk stratification infrastructure for the OPPS, one approach to limiting OPPS payment for healthcare-associated conditions in the short term could be to pay for all services provided in the encounter that led to the healthcare-associated condition at the same reduced rate that would be paid to a hospital that failed to meet the quality reporting requirements. Currently, this would mean that the hospital payment for an encounter where a healthcare-associated condition resulted would be based on the OPPS conversion factor reduced by a 2 percentage point reduction to the market basket increase for the year. Alternatively, a flat case rate reduction percentage could be considered for all, or a subset, of services provided in the clinical encounter. This reduction could potentially be empirically derived from analyzing the costs of subsets of OPPS claims for Medicare beneficiaries with and without healthcare-associated

[4] Centers for Disease Control and Prevention: Morbidity and Mortality Weekly Report, March 28, 2008, Vol. 57, No. RR–1. Available at: *http://cdc.gov/mmwr/mmwr_rr.html.*

conditions, or could possibly be developed through analysis of the IPPS payment relationship between MS–DRGs with the presence or absence of a CC or an MCC. Any reduction in OPPS payment should also be applied to the 20-percent beneficiary copayment requirement for the OPPS so that the beneficiary's cost sharing (which is paid for each service furnished) would not rise as a proportion of the total Medicare payment when the payment would be reduced. Furthermore, the hospital should not be able to bill the beneficiary for OPPS services that either would not be paid or would be paid at an adjusted amount under an OPPS healthcare-associated conditions payment provision.

In contrast to the payment limitation approach used for the IPPS, we explained in the CY 2009 OPPS/ASC proposed rule that we recognized that neither of the possible payment limitation approaches discussed above would specifically target the separate OPPS payment for those additional hospital services provided as a result of the healthcare-associated condition (as opposed to the payment for the services that initially brought the beneficiary to the HOPD). We noted that the current OPPS payment structure sets a single payment rate for a service based on the APC median cost from all claims for services assigned to the APC, including cases with healthcare-associated conditions as well as cases without healthcare-associated conditions. Therefore, we stated that we believe it could be appropriate to reduce the single OPPS payment through one of the general payment limitation approaches described above for the OPPS because any additional costs of encounters resulting in healthcare-associated conditions would already be included in the base OPPS payment rates for most OPPS services. We specifically requested public comment on these possibilities or other ways to use or adapt the current OPPS infrastructure for purposes of implementing a healthcare-associated conditions payment provision.

As discussed in the CY 2009 OPPS/ASC proposed rule (73 FR 41551), a related application of the broad principle behind the IPPS hospital-acquired conditions payment provision could be accomplished through Medicare secondary payer policy by requiring the provider that failed to prevent the occurrence of a healthcare-associated condition in one setting to pay for all or part of the necessary followup care in a second setting. This would shield the Medicare program from paying for the downstream effects of a condition acquired in the first setting but treated in the second setting. This type of scenario would likely be common for certain healthcare-associated conditions related to HOPD care, given the relatively short lengths of stay for HOPD services. We indicated that we were interested in receiving public comments regarding this more general approach to extending beyond the inpatient setting the concept of not providing Medicare payment for healthcare-associated conditions, including the advantages and disadvantages of taking a payment system by payment system approach or of adopting the general principle of holding the provider that failed to prevent the occurrence of a condition in one setting responsible for payment of the followup care in any other setting.

Comment: Several commenters fully supported expanding the IPPS hospital-acquired conditions policy to HOPDs and ASCs. They encouraged CMS to expand the policy as supported by the clinical evidence base in order to improve patient outcomes and work toward aligning payment toward higher value across settings. They also expressed full support for the criteria used and the four specific healthcare-associated conditions discussed.

However, the majority of commenters had specific concerns with the suggested conditions or concerns about CMS' authority and ability to fairly implement such a policy for outpatient settings. Some commenters supported the general idea of a healthcare-associated conditions payment policy for HOPDs, while others opposed any expansion of the IPPS hospital-acquired conditions payment provision to other settings. Some commenters stated that CMS should not/cannot implement an OPPS healthcare-associated condition payment policy without explicit statutory authority. Many commenters also stated that CMS should not implement a related policy in HOPDs, ASCs, or physicians' offices without gathering several years of data and gaining implementation experience for IPPS hospital-acquired conditions. Several commenters recommended that CMS develop an advisory panel of clinicians and scientists, including both academic researchers and clinicians active in patient care in HOPDs, to provide the agency with assistance in developing the policy.

Response: Given that so much medical care is now provided to Medicare beneficiaries outside of the hospital inpatient setting, we believe that extending a healthcare-associated conditions payment policy to the OPPS is an important and essential next step in Medicare's focus on quality and value. We believe it is fully appropriate to adopt a policy of not paying more for medical care that harms patients or leads to complications that could have been prevented. Because the high volume services delivered in the HOPD are so varied, we believe a healthcare-associated conditions payment policy in the HOPD would allow CMS to extend its quality activities and drive quality and value by stimulating behaviors that are patient-centered and focus on the continuum of care and patient safety goals. The hospital community has already begun to focus on quality in the HOPD by submitting relevant quality data through the HOP QDRP, and hospital participation in the program determines the hospital's annual payment update. We believe that a healthcare-associated conditions payment policy would take this initial effort to the next level of quality improvement.

Moreover, we believe that we have statutory authority to implement a healthcare-associated conditions payment policy for the OPPS. Specifically, section 1833(t)(2)(E) of the Act provides that the '' * * * Secretary shall establish, in a budget neutral manner, * * * adjustments as determined to be necessary to ensure equitable payments * * *.'' Consistent with our usual practice, we would pursue the development and adoption of such a policy through our annual notice and comment rulemaking to update the OPPS. We believe an urgent and compelling rationale exists for considering a healthcare-associated conditions payment policy necessary to ensuring equitable payments under the OPPS. While we plan to attend to and learn from our experience with the implementation and ongoing development of the IPPS hospital-acquired conditions policy, we do not believe that it is necessary for us to gain years of experience with that program before pursuing a healthcare-associated conditions payment policy for the OPPS. As the commenters pointed out, the IPPS and OPPS are very different payment systems, and we believe that the most appropriate course at this point is to consider a healthcare-associated conditions payment policy for the OPPS that takes into account the most current and emerging knowledge and experience in this rapidly evolving area of health care policy.

We appreciate the challenges raised by commenters, and we will continue to evaluate and seek input from stakeholders and other potential collaborators to identify healthcare-associated conditions that are

meaningful in the HOPD setting and may propose payment adjustments for them, as appropriate, in a future OPPS annual rulemaking cycle, to ensure equitable payments. We understand the importance and value of identifying appropriate collaborators to work with us as we develop the policy, identify conditions, and address implementation issues. Therefore, we intend to continue an open dialogue with stakeholders regarding all issues relevant to the development of a healthcare-associated conditions policy over the upcoming months, which we anticipate will begin this winter with an IPPS/OPPS hospital-acquired/healthcare-associated conditions listening session, jointly sponsored with the CDC.

Comment: Some commenters suggested that CMS should reconsider the criteria for possible candidate OPPS conditions and specifically define ''reasonably preventable'' for the HOPD setting. Several commenters stated that clinically-proven guidelines for prevention should be available and that there should be solid evidence that, by following the guidelines, the likelihood of the occurrence of an event can be reduced to zero or near zero. Other commenters suggested that CMS define rates or frequencies of ''reasonably preventable'' events and design a strategy to both reward and penalize hospitals based on data-driven findings that would ultimately also serve to drive quality improvement.

Several commenters addressed some of the potential specific healthcare-associated conditions discussed in the CY 2009 OPPS/ASC proposed rule (73 FR 41549), as well as suggested other conditions that might be considered or should not be considered. Two commenters were concerned with the potential inclusion of falls and trauma as a condition. Another commenter requested that hospitals providing rehabilitation therapy services be exempt from a healthcare-associated conditions payment policy because of the inherent risk of falls associated with the provision of rehabilitation services. In addition, one commenter requested that if CMS were to implement a policy for healthcare-associated conditions in the HOPD setting, CMS should continue the established IPPS policy of excluding *Staphylococcus aureus* septicemia and methicillin-resistant *Staphylococcus aureus* infection because these infections are not ''reasonably preventable.'' One commenter stated that blood is rarely transfused in the outpatient setting and, therefore, blood incompatibility should be removed from consideration. A few commenters stated that CMS should not simply incorporate all of the IPPS hospital-acquired conditions into the OPPS. Several commenters suggested that CMS consider adding serious disability or death caused by adverse events and serious disability or death caused by medication errors as future healthcare-associated conditions. Finally, several commenters recommended that CMS should use a process similar to that used for identifying IPPS hospital-acquired conditions, that is, working with the CDC, before implementation of a healthcare-associated conditions program in the HOPD setting.

Many commenters requested that CMS delay any implementation of a healthcare-associated conditions payment policy under the OPPS until adoption of ICD–10, to facilitate the collection of more accurate data and the use of E-codes. In addition, many commenters stated that the attribution of healthcare-associated conditions in the HOPD setting is difficult because patients often see multiple physicians or practitioners in multiple distinct hospital outpatient departments and settings. Finally, several commenters believed that there was a serious need to develop risk adjustment techniques to account for differences in patient severity and other patient characteristics, especially for teaching hospitals and other hospitals, such as cancer hospitals, that see many high-risk patients.

Response: We understand the commenters' concerns about the choice of conditions for a healthcare-associated conditions payment policy in the outpatient environment, and we plan to work with knowledgeable experts in hospital outpatient care to choose reasonably preventable conditions based on solid evidence for future proposed policies. Our goal is to eliminate preventable events to the extent possible, while stimulating hospitals to design system changes to minimize the occurrence of errors broadly.

We appreciate the public comments about the specific healthcare-associated conditions discussed in the CY 2009 OPPS/ASC proposed rule, as well as other suggestions made by commenters regarding other potential HOPD-specific conditions. We note that each of the four conditions discussed in the CY 2009 OPPS/ASC proposed rule is among the Serious Reportable Events (commonly referred to as ''never events'') identified by the NQF and included in the current IPPS hospital-acquired conditions payment provision. We will continue to consider each of these conditions, as well as others suggested by commenters, as we move forward to develop a healthcare-associated conditions payment policy for the OPPS. We agree that the future implementation of ICD–10 will be helpful to identify adverse events and medical errors, but we do not see the necessity of waiting for ICD–10 to initiate a healthcare-associated conditions program under the OPPS.

We agree that the OPPS APC payment methodology currently does not distinguish the severity of illness of patients being treated within each APC group. Hospital claims for both low and high severity patients contribute to the calculation of the overall median cost for the services and procedures assigned to each APC. We also understand that a process to document and capture patient comorbidities and existing complications in outpatient settings is not yet fully developed. As a result, a healthcare-associated conditions payment policy for the OPPS would need to be initiated and then incrementally refined, potentially using Serious Reportable Events as a starting point until a fair risk adjustment program could be implemented.

Likewise, we acknowledge that Medicare patients may see physicians or other practitioners in multiple HOPDs and clinics, physicians' offices, ASCs, or other settings during a given episode-of-care; therefore, accountability could be difficult to assign. While we understand that there are complexities associated with attribution in any setting, particularly ambulatory settings, complications are most likely the result of a breakdown in communication of accurate, timely, and relevant information among practitioners and providers. Consequently, we believe that expansion of healthcare-associated conditions to settings beyond the IPPS is an urgent and essential next stage in encouraging the coordination of the highest quality health care for Medicare beneficiaries.

Comment: Several commenters stated that the IPPS hospital-acquired conditions payment reduction methods would not be appropriate for the OPPS because the OPPS APC payments are HCPCS code-based and not based on diagnosis and disease severity, as is the IPPS. Several commenters suggested that without changes to the OPPS payment structure, there would be no fair or straightforward methodology for adjusting hospital payment. Several commenters recommended that CMS use a flat case rate reduction, but cautioned that this would require a comparison of costs for services between claims with healthcare-associated conditions and those without healthcare-associated conditions. The commenters also recommended several

other alternative payment mechanisms. For example, some commenters suggested episode-based payments encompassing the continuum of care that recognize and reward effective post-discharge care. Other commenters offered a data-driven approach to establish benchmark and best practice complication rates for healthcare-associated conditions where CMS could set payment rates based on average complication rates and provide evidence-based tools to help hospitals work toward lower complication rates. Several commenters argued that holding one provider responsible for payment of costs downstream would not be viable because of multiple payment systems, contractors, and providers.

Response: We appreciate the concerns of the commenters about developing a payment reduction policy associated with healthcare-associated conditions under the OPPS, given the differences between the HCPCS code-based OPPS and MS–DRG-based IPPS payment infrastructures, and we welcome consideration of the payment reduction methodologies suggested by others. We note that we received no public comments on the possibility of providing the same reduced payment rate for services in the HOPD encounter that led to the healthcare-associated condition that would be paid to a hospital that failed to meet the quality reporting requirements. We will fully consider each of the payment reduction methodologies suggested by commenters and discussed in the CY 2009 OPPS/ASC proposed rule (73 FR 41550). We also plan to continue an open dialogue with stakeholders as we move forward over the coming months toward the goal of establishing a strong connection between an OPPS healthcare-associated conditions payment policy and the delivery of the highest quality health care. We also expect that the future development and refinement of a healthcare-associated conditions payment policy, as well as POA indicators for the outpatient setting, will lead to increased communication among providers, contractors, and policymakers, as well as potentially more integrated payment for Part B services across payment systems. This, in turn, could allow for holding one provider responsible to another for payment of costs downstream for healthcare-associated conditions.

Comment: Many commenters asserted that the POA indicators in use for the IPPS hospital-acquired conditions policy beginning October 1, 2008 may need to be modified as a requirement for healthcare-associated conditions in the HOPD or ASC setting. Several commenters observed that the conditions CMS proposed for consideration (air embolism, object left in during surgery, blood incompatibility, and falls and trauma) would likely result in an inpatient admission with the healthcare-associated condition reported as present on admission. Many commenters also argued that the HOPD episode-of-care is often too short to identify whether a condition was present at the beginning of the hospital outpatient stay. They also believed that there would likely be unintended consequences to using a POA indicator for the OPPS, such as hospitals providing increased and unnecessary diagnostic testing. Several commenters claimed that having to report POA indicators for all ICD–9–CM diagnosis codes would be an administrative burden on hospitals. They requested that CMS consider narrowing hospital outpatient POA data collection to specific conditions or specific populations of beneficiaries. In addition, one commenter suggested that the entire current ICD–9–CM Official Coding Guidelines for POA would have to be evaluated and possibly revised or rewritten for outpatient settings, due to potential complications of collecting POA information in the outpatient setting using the current guidelines. A number of commenters believed the term ''present on admission'' was not applicable to the HOPD setting and suggested the term would need to be changed to ''present on arrival.'' Finally, some commenters suggested that a ''present on encounter'' indicator or another form of incorporation of pre-existing conditions into an episode-of-care might be more useful than a POA indicator because care may extend into other settings or to other caregivers or practitioners.

Response: We acknowledge that the POA indicator was designed for hospital inpatient use and would need to be refined for the HOPD setting, both to accommodate events occurring in the hospital outpatient setting that directly result in hospital admission (for example, air embolism), as well as to allow identification of HOPD initiated healthcare-associated conditions that may become apparent distinct from the date of the initiating event (for example, object left in during surgery). We believe that accountability of a single hospital provider for the quality of medical care provided across its outpatient and inpatient settings should be a central component of patient-centered care coordination and effective implementation of hospital-acquired and healthcare-associated conditions payment policies. For instance, we do not believe that a preventable condition acquired in the HOPD that results in an inpatient admission should be considered POA because it occurred before there was a physician's written order to admit the patient. In such a case, it was the hospital's care that caused the condition and the inpatient admission and, in our view, the condition should not be considered as a complication or major complication in determining the Medicare inpatient hospital payment. It would be clinically non-intuitive and counter to the goals of patient safety and value-based purchasing if healthcare-associated conditions that developed during an HOPD encounter and resulted in an inpatient admission could not be identified through our coding systems and, therefore, an appropriate payment adjustment could not be provided. We will raise this issue with the NUBC, which is responsible for maintaining the POA reporting definitions. In addition, we believe that it would be both inappropriate and a disservice to beneficiaries for hospitals to engage in activities such as delayed admission or transfer between a provider's facilities or satellites in order to avoid an IPPS hospital-acquired condition payment reduction.

It is imperative that as we consider expansion of the IPPS hospital-acquired conditions payment policy to other settings, we synchronize policies across Medicare payment systems. Therefore, we look forward to working with the NUBC to develop POA indicators appropriate to outpatient settings. We also plan to work with the NUBC to refine and update the POA reporting definitions so that we can accomplish the goals of the IPPS hospital-acquired and OPPS healthcare-associated conditions policies of holding a provider responsible for preventable conditions attributable to care provided in its own outpatient or inpatient settings, while also ensuring that the reporting definitions continue to be appropriate and effective for nonhospital-acquired conditions payment and research purposes. As we move toward an OPPS healthcare-associated conditions payment policy, we will work with hospitals and other stakeholders to ensure that reporting of conditions in outpatient settings could be accomplished in a way that would be administratively manageable for hospitals, while discouraging potential undesirable effects on beneficiaries and the Medicare program, such as overutilization of diagnostic testing.

In summary, we thank commenters for their thoughtful responses and suggestions to our CY 2009 OPPS/ASC proposed rule discussion and questions regarding the potential for extension of the IPPS hospital-acquired conditions payment provision to outpatient settings through a healthcare-associated conditions payment policy. We view addressing the ongoing problem of preventable healthcare-associated conditions in outpatient settings, including the HOPD, as a key value-based purchasing strategy to sharpen the focus on such improvements beyond hospital inpatient care to those settings where the majority of Medicare beneficiaries receive most of their health care services. We look forward to continuing to work with stakeholders to improve the quality, safety, and value of healthcare provided to Medicare beneficiaries, beginning with the joint IPPS/OPPS listening session that we anticipate holding this winter.

XVIII. Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; Policy Clarification

On March 30, 2007, we published in the **Federal Register** (72 FR 15198) a final rule that set forth the requirements that heart, heart-lung, intestine, kidney, lung, and pancreas transplant centers must meet to participate as Medicare-approved transplant centers. These requirements included procedures for approval and re-approval, as well as disapproval, of transplant centers. In that final rule, we summarized and responded to the public comments that we had received on a preceding proposed rule published in the **Federal Register** on February 4, 2005 (70 FR 6140).

This final rule clarifies and revises several statements of policy that were provided in the March 30, 2007 final rule as responses to public comments received on the proposed rule. Specifically, among the public comments received, a few commenters recommended that ''a center should be allowed to continue Medicare participation pending exhaustion of any appeals, provided that its treatment of Medicare beneficiaries does not jeopardize their health and safety.'' In the March 30, 2007 final rule (72 FR 15242), we responded, in part, to this public comment by stating that ''[i]f a transplant center appeals a termination of Medicare approval under 42 CFR part 498, the termination will not occur until the appeals process, if any, is completed.'' This statement is contrary to longstanding Medicare policy.

In addition, in the February 4, 2005 proposed rule, we had proposed at § 482.104(c)(2) to require a transplant center being terminated to inform patients on the center's waiting list of that fact 30 days prior to the termination. One commenter who responded to the proposed rule recommended that CMS modify the proposed 30-day notification requirement by adding language to indicate that patients on the center's waiting list must be informed 30 days prior to the termination ''and following the exhaustion of all appeals provided pursuant to [part] 498.'' In the preamble to the March 30, 2007 final rule at page 15248, we responded to this comment in part by stating that ''[i]n most cases Medicare providers and suppliers are permitted to continue to participate in Medicare while an appeal is pending. * * *'' This response statement is also contrary to longstanding Medicare policy.

In this final rule, we are clarifying the two responses in the preamble of the March 30, 2007 final rule to make clear that longstanding Medicare policy does not permit a provider to continue to participate in the Medicare program until the provider has exhausted all appeals. In fact, it has been the consistent policy of this Department for more than 30 years to make provider agreement terminations, and most alternative sanctions, effective prior to the running of the administrative appeals process. Where the matter has arisen in litigation over the years, the courts have upheld this position. We cite the following court cases as examples: *Cathedral Rock of North College Hill, Inc.* v. *Shalala,* 223 F.3d 354 (6th Cir. 2000); *Caton Ridge Nursing Home, Inc.* v. *Califano,* 596 F.2d 608 (4th Cir. 1979); and *Geriatrics, Inc.* v. *Harris,* 640 F.2d 262 (10th Cir. 1981). While there are many legal arguments that have been made in support of this view, the Department has taken this position largely based on its underlying belief that patients or residents of health care facilities should not be subjected to continued poor quality of care for the pendency of an appeal which can be lengthy in duration. In this context, the interests of providers wanting to stay in the program must be of secondary importance to the well-being of the Medicare patient population.

Thus, if a provider, such as a transplant center, appeals a termination of Medicare approval under 42 CFR part 498, termination occurs on the date established by CMS, and termination will be prior to the onset of any appeals process, whether or not the deficiency poses immediate jeopardy to the health and safety of patients.

Therefore, in this final rule, we are clarifying the response to comment language of the preamble of the March 30, 2007 final rule at page 15242 by revising it to read ''Thus, if a transplant center appeals a termination of Medicare approval under 42 CFR part 498, the termination *will* occur *before* the appeals process, if any, begins.'' (Emphasis added) We are clarifying the response to comment language of the preamble of the March 30, 2007 final rule at page 15248 by revising it to read ''Medicare providers and suppliers are not entitled to have their program participation continue during the pendency of the administrative appeals process.'' We note that no change is being made to the regulation text because the regulation itself does not call for a prior hearing. Our intent is only to clarify and correct earlier preamble statements that ran contrary to a longstanding policy of this Department.

This clarification does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

The revised preamble statements merely clarify existing policy and, therefore, the impact is negligible.

XIX. Files Available to the Public via the Internet

A. Information in Addenda Related to the CY 2009 Hospital OPPS

Addenda A and B to this final rule with comment period provide various data pertaining to the CY 2009 payment for items and services under the OPPS. Addendum A, which includes a list of all APCs to be payable under the OPPS, and Addendum B, which includes a list of all active HCPCS codes and all currently active HCPCS codes that will be discontinued at the end of CY 2008 with their assigned 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.hhs.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 APC assignment, identified as Addendum C.

Addendum D1 defines the payment status indicators that are used in Addenda A and B. Addendum D2

defines the comment indicators that are used in Addendum B. Addendum E lists the HCPCS codes that only are payable to hospitals as inpatient procedures and are not payable under the OPPS. Addendum L contains the out-migration wage adjustment for CY 2009. Addendum M lists the HCPCS codes that are members of a composite APC and identifies the composite APC to which each is assigned. This addendum also identifies the status indicator for the code and a comment indicator if there is a change in the code's status with regard to its membership in the composite APC. Each of the HCPCS codes included in Addendum M has a single procedure payment APC, listed in Addendum B, to which it is assigned when the criteria for assignment to the composite APC are not met. When the criteria for payment of the code through the composite APC are met, one unit of the composite APC payment is paid, thereby providing packaged payment for all services that are assigned to the composite APC according to the specific I/OCE logic that applies to the APC. We refer readers to the discussion of composite APCs in section II.A.2.e. of this final rule with comment period 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.hhs.gov/HospitalOutpatientPPS/.*

B. Information in Addenda Related to the CY 2009 ASC Payment System

Addenda AA and BB to this final rule with comment period provide various data pertaining to the CY 2009 payment for ASC covered surgical procedures and covered ancillary services for which ASCs may receive separate payment. Addendum AA lists the ASC covered surgical procedures and the CY 2009 ASC payment indicators and payment rates for each procedure. Addendum BB displays the ASC covered ancillary services and their CY 2009 payment indicators and payment rates. All relative payment weights and payment rates for CY 2009 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 final CY 2009 OPPS and MPFS ratesetting information.

Addendum DD1 defines the payment indicators that are used in Addenda AA and BB. Addendum DD2 defines the comment indicators that are used in Addenda AA and BB.

Addendum EE (available only on the Internet) lists the surgical procedures that are excluded from Medicare payment if furnished in ASCs. The excluded procedures listed in Addendum EE are surgical procedures that are either assigned to the OPPS inpatient list, are not covered by Medicare, are reported using a CPT unlisted code, or have been determined to pose a significant safety risk 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.hhs.gov/ASCPayment/.* The MPFS data files are located at: *http://www.cms.hhs.gov/PhysicianFeeSched/.*

The links to all of the FY 2009 IPPS wage index related tables (that are to be used for the CY 2009 OPPS) that were published as tentative and final in the FY 2009 IPPS final rule (73 FR 48779 through 49021) and that were issued as final in a subsequent document published in the **Federal Register** on October 3, 2008 (73 FR 57888) are accessible on the CMS Web site at: *http://www.cms.hhs.gov/AcuteInpatientPPS/WIFN.*

XX. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and 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 PRA 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. ASC Conditions for Coverage Collections

In the August 31, 2007 ASC CfCs proposed rule (72 FR 50478), we solicited public comments on each of the issues outlined under section XX.A. of this preamble for the sections under items XX.B.1. through 4. below included in the proposed rule that contain information collection requirements.

1. Condition for Coverage—Governing Body and Management (§ 416.41)

Section 416.41 sets out the conditions for coverage related to the governing body and management of ASCs. Each ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. Section 416.41(b)(3) states that, as a condition for coverage, an ASC must have a written transfer agreement with the hospital as referenced in §§ 416.41(b)(1) and (b)(2).

The burden associated with this requirement is the time and effort involved in the ASC having a written transfer agreement with the hospital receiving the transfer. This requirement is subject to the PRA, and is currently approved under OMB No. 0938–0266, with an expiration date of June 30, 2011.

Section 416.41(c)(1) requires that an ASC maintain a written disaster preparedness plan that provides for the emergency care of patients in the event of fire, natural disaster, functional failure of equipment, or other unexplained circumstances that are likely to threaten personal health and safety. Section 416.41(c)(3) requires that an ASC complete a written evaluation of each drill conducted to test the effectiveness of the disaster preparedness plan.

The burden associated with the requirements in §§ 416.41(c)(1) and (c)(3) is the time and effort necessary to draft and maintain the written disaster preparedness plan. In addition, there is burden associated with drafting and maintaining the reports on the effectiveness of the plan. We estimate that an administrator, earning $49.00 per hour, would be largely responsible for developing the plan and for managing the yearly drills and evaluations. We are estimating that the yearly cost for one ASC to develop and implement a disaster preparedness plan will be approximately 4 hours at $49.00 per hour, with a net cost of $196.00 per ASC. The total cost for all ASCs is estimated to be $999,600.

We did not receive any public comments on these information collection requirements.

2. Condition for Coverage—Quality Assessment and Performance Improvement (§ 416.43)

Section 416.43 sets out the conditions for coverage for quality assessment and performance improvement. ASCs,

through the governing body and with the active participation of the medical staff, must develop, implement, and maintain an ongoing, data-driven QAPI program. This section outlines the standards for the scope of the QAPI program, the use of quality indicator data, the prioritization of performance improvement program activities, the complexity of performance improvement projects, and the responsibilities of ASC governing bodies. Specifically, § 416.43(d)(2) states that an ASC must fully document the performance improvement projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the results of the project.

The burden associated with this requirement is the time and effort involved in collecting, analyzing, and documenting the performance improvement projects. We estimate that each ASC would spend 18 hours a year collecting, analyzing, and documenting the findings. These activities would most likely be managed by the ASC's administrator. Based on an hourly rate of $49.00, the total cost of these activities is estimated to be $882 per ASC.

We did not receive any public comments on this information collection requirement.

3. Condition for Coverage—Patient Rights (§ 416.50)

Section 416.50 sets out the requirements an ASC must meet when informing a patient of his or her rights, in addition to requirements for the protection and promotion of these rights. Section 416.50(a)(1) requires that an ASC provide the patient or, as appropriate, the patient's representative with verbal and written notice of the patient's rights in advance of the procedure to be performed at the ASC and in a language and manner that the patient or patient's representative understands.

The burden associated with these requirements is the time and effort required to inform the patient or, as appropriate, the patient's representative of the patient's rights. Because ASCs must notify patients either verbally or in writing in advance of the patient coming under the ASC's care, ASCs may choose to mail the patient rights notification to the patient along with the pre-surgical information, the physician's financial interests or ownership, and the advance directives. Generally, the most effective and efficient manner to furnish a notice of rights is to initially develop a general notice which can be subsequently discussed and/or distributed as needed. We expect that an ASC will use this simple and inexpensive approach in order to meet this requirement. In response to the needs of their specific patient populations, some ASCs might choose to have their patient rights notification written in the predominant language(s) of their patients. More than likely, this message would be written by a registered nurse or similar professional. A typical message might be in three parts: An introduction; the information section; and a section for follow-up questions and issues. We expect the effort to develop this one-time message would not exceed 1 hour at a cost of $39.00 for each ASC. We believe that this would be a one-time cost for ASCs and estimate that the total costs would be $198,900 for all ASCs.

Section 416.50(a)(2)(i) requires ASCs to provide the patient or representative with information concerning its policies on advance directives, including a description of applicable State law. Section 416.50(a)(2)(iii) requires documentation in a prominent part of the patient's medical record that indicates whether or not the patient has executed an advance directive. The burden associated with these requirements is the time and effort necessary for disseminating the information to the patient and maintaining the necessary documentation in the medical record. ASCs mail information to their patients concerning documentation that must be completed prior to the surgical procedure. Dissemination of the advance directives information will result in the inclusion of one additional sheet of paper in the ASC's mailing packet. In addition, as a matter of both law and ethics, health care providers are generally expected to provide care that conforms to the wishes and priorities of the patient. Thus, information on advance directives should be communicated in a way that effectively notifies patients of their right to complete an advance directive before they agree to use the facility's services because the facility's policy could be important to a patient's choice of whether to use that facility. Providing advance directives information to patients prior to the patient's first visit to the ASC is typically done by ASCs even though it is not specifically federally mandated.

However, arguably, informing patients concerning advance directives is in keeping with the current requirement concerning documentation of properly executed informed patient consent found at § 416.47 and would be considered part of the ASC's standard operating costs. Thus, while these requirements are subject to the PRA, we believe they would constitute usual and customary business practices. Pursuant to 5 CFR 1320.3(b)(2), we will not include these activities in the PRA analysis.

Section 416.50(a)(3) imposes both recordkeeping and reporting requirements. Specifically, § 416.50((a)(3)(ii) states that an ASC must fully document all alleged violations relating, but not limited to, mistreatment, neglect, verbal, mental, sexual or physical abuse. In addition, at § 416.50(a)(3)(iii), an ASC must immediately report the allegations to a person in authority in the ASC. Under § 416.50(a)(3)(iv), the ASC must immediately report substantiated allegations to the State and local bodies having jurisdiction, and the State survey agency if warranted. In addition, § 416.50(a)(3)(v) requires an ASC to document how the grievance was addressed. The ASC must also provide the patient with a written notice of its decision.

The burden associated with this requirement is the time and effort necessary to fully document the alleged violation or complaint, disclose the written notice to each patient who filed a grievance, and report the alleged violations to the aforementioned entities. We estimate that, on average, it will take each ASC 15 minutes at a cost of $39.00 an hour to develop and disseminate 12 notices on an annual basis (3 hours per ASC), for a total ASC burden of 15,300 hours at a cost of $596,700.

Since ASCs began operating under Medicare in 1982, they have been required to provide information to patients about the procedures to be performed. This information is provided to patients by way of the informed patient consent in the current regulation. ASCs are also responsible for providing patients with information concerning expected outcomes. The final rule requires that ASCs continue this practice. Therefore, we do not anticipate that ASCs will incur significant costs associated with this requirement.

While these requirements are subject to the PRA, we believe they would constitute a usual and customary business practice. Pursuant to 5 CFR 1320.3(b)(2), we will not include these activities in the PRA analysis.

We did not receive any public comments on these information collection requirements.

4. Condition for Coverage—Patient Admission, Assessment, and Discharge (§ 416.52)

Section 416.52(a) requires each patient to have a comprehensive medical history and physical assessment no more than 30 days before the scheduled surgery date. The patient also must have a pre-surgical assessment which must occur upon admission. Section 416.52(b) requires that the patient's post-surgical condition must be assessed and documented in the medical record and that the patient's post-surgical needs must be addressed and included in the discharge notes. Section 416.52(c) requires that ASCs provide each patient written discharge instructions and ensure that each patient receives a discharge order signed by a physician or other qualified practitioner. ASCs also must ensure all patients are discharged in the company of a responsible adult.

The burden associated with these requirements is the time and effort necessary to perform the assessments and to document the information in the medical record. However, performing patient assessments and documenting medical records is normal and customary business practice for health care providers. Therefore, while these requirements are subject to the PRA, the associated burden is exempt as it meets the requirements set forth in 5 CFR 1320.3(b)(2).

We did not receive any public comments on these information collection requirements.

5. Revisions to the CfC on Infection Control in This Final Rule (§ 416.51)

In § 416.51 of the August 31, 2007 ASC CfCs proposed rule, we included a CfC on infection control, which specified that an ASC must (1) provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice and (2) maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. The program would be required to designate a qualified professional who has training in infection control, integrate the infection control program into the ASC's QAPI program, and be responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.

As discussed in section XV.B.2.b.(5) of this preamble of this final rule, in response to public comments received, we are revising § 416.51(b) to specify that the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.

The burden associated with this requirement is the time and effort necessary to document the consideration, selection, and implementation of the nationally recognized infection control guidelines information in the program. We believe that the time needed for the required documentation would be negligible. Therefore, while this requirement is subject to the PRA, the associated burden is exempt as it meets the requirements set forth in 5 CFR 1320.3(b)(2).

f. Effects of the Patient Admission, Assessment, and Discharge Provision (§ 416.52)

We are finalizing this new condition because it represents the current standard of practice and does not pose additional burden.

(1) Effects of the Admission and Pre-Surgical Assessment Provision

We are requiring the completion of a comprehensive medical history and physical assessment no more than 30 days before the day of the scheduled surgery. It is very unlikely that the comprehensive medical history will be completed at the ASC. Therefore, there is unlikely to be any ASC burden associated with this requirement.

We are requiring that a pre-surgical assessment be completed upon admission to the ASC. Existing regulations at § 416.42(a) require a physician to examine the patient immediately before surgery to evaluate the risks involved in administering anesthesia and performing the procedure. Physicians must determine that patients, including those at high risk, are able to undergo the surgery itself and be able to manage recovery. Pre-surgical assessments represent a current standard of community practice, are currently required under existing regulations, and, therefore, do not pose additional burden.

To ensure the ASC health care team has all patient information available when needed, the medical history and physical assessment must be placed in the patient's medical record before the surgical procedure is started. There is no burden associated with this requirement.

(2) Effects of the Post-Surgical Assessment Provision

The post-surgical assessment requires the ASC to ensure the patient's post-surgical condition is documented in the medical record by a physician or other qualified practitioner in accordance with State law and ASC policy, and the patient's post-surgical needs addressed and included in the discharge notes. Post-surgical assessments, located in the current regulation under surgical services, reflect ASC standard of practice, and therefore, do not pose additional burden.

(3) Effects of the Discharge Provision

The ASC is required to provide each patient with discharge instructions and ensure each patient has a signed discharge order, any needed overnight supplies and physician contact information for followup care or an appointment. Requiring the patient to have a signed discharge order, discharge instructions, any immediate overnight supplies that may be needed, and physician contact information when the patient leaves the ASC is standard practice. Therefore, we do not believe this is a new burden for ASCs.

Therefore, while these requirements are subject to the PRA, the associated burden is exempt as it meets the requirements set forth in 5 CFR 1320.3(b)(2).

C. Associated Information Collections Not Specified in Regulatory Text

This final rule with comment period does not impose any information collection requirements through regulatory text. However, this final rule with comment period makes reference to one associated information collection concerning the HOP QDRP that is not discussed in the regulatory text. The following is a discussion of this collection, for which we solicited public comment in the CY 2009 OPPS/ASC proposed rule (73 FR 41552).

Section 419.43(h) requires hospitals, in order to qualify for the full annual update, to submit quality data to CMS, as specified by CMS. In section XVI.C.1. of the CY 2009 OPPS/ASC proposed rule (73 FR 41541), we proposed the specific requirements related to the data that must be submitted for the update for CY 2010. The burden associated with this section is the time and effort associated with collecting and submitting the data, completing participating forms and submitting charts for chart audit validation. In the CY 2009 OPPS/ASC proposed rule (73 FR 41552), we estimated that there will be approximately 3,500 respondents per year.

For hospitals to collect and submit the information on the required measures, we estimated it will take 30 minutes per sampled case. In this final rule with comment period, we have reduced the burden associated with our proposed data submission requirements by making hospital submission of the aggregate numbers of outpatient episodes of care which are eligible for submission under the HOP QDRP voluntary, instead of requiring this submission as we proposed. Thus, although in the proposed rule based on an estimated 10 percent sample size and estimated populations of 2.5 to 5 million outpatient visits per measure, we estimated a total of 1,800,000 cases per year, the changes in this final rule with comment period will reduce this burden.

In addition, in the proposed rule we estimated that completing participation forms will require approximately 4 hours per hospital per year. (Hospitals that continue to participate in the HOP QDRP only have to complete the participation form in the first year that they participate.) We expected the burden for all of these hospitals to total 914,000 hours per year.

For CY 2010, we proposed that the proposed validation process would require a random sample of 800 participating hospitals to submit 50 charts on an annual basis. The burden associated with this requirement is the time and effort associated with collecting, copying, and submitting these charts. It would take approximately 20 hours per hospital to submit the 50 charts. There would be a total of approximately 40,000 charts (800 hospitals × 50 charts per hospital) submitted by the hospitals to CMS for a total burden of 16,000 hours. Therefore, the total burden for all hospitals would be 930,000 hours per year.

In this final rule with comment period we have revised the validation process. The validation process will be used a test to provide feedback to all participating hospitals, but will not affect CY 2010 payment determinations. We will still use a sample of 800 participating hospitals, but we will sample 50 or less cases per hospital. Thus, we believe that the burden for the validation process will be somewhat less than our original estimate, although we cannot determine how much less until we determine the final number of cases sampled.

We did not receive any public comments specifically regarding these burden estimates. We believe that our proposed estimates are still valid for this final rule with comment period, although we expect that the actual burden will be somewhat reduced by the changes from the proposed rule adopted in this final rule with comment period discussed above.

We are requesting OMB's emergency review and approval of the information collection requirements in §§ 416.41(c)(1) and (c)(3), 416.43, and 416.50. Emergency review and approval is necessary to ensure that these requirements are approved before the effective date of these provisions.

If you comment on these information collection and record keeping requirements, please mail copies directly to the following by the date listed in the ''DATES'' section of this final rule with comment period:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, *Attn.:* William Parham, CMS–1404–FC, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, *Attn:* CMS Desk Officer, CMS–1404–FC Fax (202) 395–6974.

XXI. Waiver of Proposed Rulemaking

A. Requirements for Waivers

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA). The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. However, this procedure can be waived if the Secretary finds, for good cause, that the notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the rule.

B. OPPS Regulations Update to 42 CFR 419.43(d)(1)(i)(B)

We are making a technical correction to § 419.43(d)(1)(i)(B) to appropriately reference § 419.66. The correcting amendment to § 419.43(d)(1)(i)(B) merely removes the phrase ''paragraph (e) of this section'' and adds in its place the correct cross-reference ''§ 419.66.'' As this correction does not make substantive changes to any underlying policy and is purely technical in nature, we find good cause to waive notice-and-comment procedures as unnecessary.

C. OPPS Regulations Update to 42 CFR 419.43(f)

We are making a technical conforming amendment to § 419.43(f) which sets forth our longstanding, consistent policy to exclude certain items and services from eligibility for outlier payments. Under our longstanding policy, drugs and biologicals, as well as items paid at charges adjusted to cost by application of a hospital-specific CCR are excluded from the payment adjustment in § 419.43(d). In the past, we updated the regulations at § 419.43(f) to specifically identify those items paid at charges adjusted to cost by a hospital-specific CCR that we exclude from this adjustment (for example, brachytherapy sources). We are now specifying in a general manner that items paid at charges adjusted to cost are not eligible for the adjustment in § 419.43(d) (rather than specifically listing all items that are paid at charges adjusted to cost and that are excluded from the payment adjustment in § 419.43(d)). This technical conforming amendment reflects our existing policy which has previously been subject to notice-and-comment procedures. Therefore, we find good cause to waive notice-and-comment procedures as unnecessary.

D. OPPS Regulations Update to 42 CFR 419.43(g)(4)

We are making a correcting amendment to § 419.43(g)(4) which sets forth our longstanding, consistent policy to exclude items paid at charges adjusted to cost by application of a hospital-specific CCR from the payment adjustment in § 419.43(g)(4). Instead of annually updating the regulations at § 419.43 to specifically identify those items paid at charges adjusted to cost, for administrative ease and convenience, § 419.43(g)(4) now specifies in a general manner that items and services paid at charges adjusted to cost by a hospital-specific CCR are not eligible for the adjustment in § 419.43(g)(2). This correcting amendment does not alter our longstanding, consistent policy regarding items paid at charges adjusted to cost by application of a hospital-specific CCR. As these changes reflect existing policy and the substantive policies have already undergone notice-and-comment procedures, we find good cause to waive notice-and-comment procedures as unnecessary.

E. OPPS Regulations Update to 42 CFR 419.70

We are revising § 419.70(d)(2), (d)(4), and (d)(5) of the regulations to make technical corrections and to incorporate nondiscretionary provisions of section 147 of Public Law 110–275 (as described in sections I.F.5. and II.E.1. of this final rule with comment period) with respect to the extension and expansion of the Medicare hold harmless provision under the OPPS for certain hospitals. We note that Public Law 110–275 was enacted on July 15, 2008, subsequent to issuance of the CY 2009 OPPS/ASC proposed rule. Because the rule makes conforming changes to the regulation in order to implement section 147 of Public Law 110–275, we find good cause to waive notice-and-comment procedures as unnecessary.

In the case of the correcting amendments to §§ 419.70(e), 419.70(g), and 419.70(i), we merely substitute the word ''paragraph'' with the word ''section'' in order to correct inaccurate cross-references. These corrections do not make substantive changes to any underlying policy and are purely technical in nature. Therefore, we find good cause to waive notice-and-comment procedures as unnecessary.''

In addition, as explained previously in this final rule with comment period, we are substituting the word ''paragraph'' with the word ''part'' in § 419.70(d)(2) in order to more precisely capture existing policy and to correct an inaccurate cross-reference. This change is technical in nature and does not change the substantive underlying policy. Therefore, we find good cause to waive notice-and-comment procedures as unnecessary.

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 final rule with comment period, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document(s).

XXIII. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this final rule with comment period (CMS–1404–FC) and the two final rules (CMS–3887–F and CMS 3835–F–1) as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), as amended by Executive Order 13258, the Regulatory Flexibility Act (RFA) (September 19, 1980, Public Law 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 (as amended by Executive Order 13258) 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 with economically significant effects ($100 million or more in any 1 year).

We estimate that the effects of the OPPS provisions that will be implemented by this final rule with comment period will result in expenditures exceeding $100 million in any 1 year. We estimate the total increase (from changes in this final rule with comment period as well as enrollment, utilization, and case-mix changes) in expenditures under the OPPS for CY 2009 compared to CY 2008 to be approximately $1.6 billion.

We estimate that the effects of the changes to the ASC payment system provisions for CY 2009 (such as adding 14 procedures that were previously excluded to the CY 2009 ASC list of covered surgical procedures and designating 8 additional procedures as office-based) will have no net effect on Medicare expenditures in CY 2009 compared to the level of expenditures in CY 2008. A more detailed discussion of the effects of the changes to the ASC payment system for CY 2009 is provided in section XXIII.C. of this final rule with comment period.

This final rule with comment period is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis that, to the best of our ability, presents the costs and benefits of the rulemaking. Table 53 and Table 54 of this final rule with comment period display the redistributional impact of the CY 2009 changes on ASC payment, grouped by specialty area and then by procedures with the greatest ASC expenditures, respectively.

We have determined that the final rule for the ASC CfCs is not a major rule because the overall economic impact for all the new CfCs is estimated to be $26.2 million annually.

We have determined that the final rule that contains clarification regarding the Secretary's ability to terminate Medicare providers and suppliers (that is, relating specifically to transplant centers) during an appeal of a determination that affects participation in the Medicare program will have no net effect on Medicare expenditures.

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; ambulatory surgical centers having revenues of $10 million or less in any 1 year). (For details on the latest standards for health care providers, we refer readers to 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 final rule with comment period will have a significant impact on a substantial number of small entities.

In relation to the final rule on the ASC CfCs, we estimate there are approximately 5,100 Medicare-participating ASCs (that includes both deemed and non-deemed facilities) with average admissions of approximately 1,240 patients per ASC (based on the number of patients seen in ASCs in 2008 divided by the number of ASCs in 2008). As stated earlier, most ASCs are considered to be small entities, either by nonprofit status or by having revenues of $7 million to $34.5 million in any 1 year. The cost of this final rule is less than 1 percent of the total ASC Medicare revenue per facility. According to the CMS national expenditure data, Medicare paid approximately $3 billion to ASCs in 2007.

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 604 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 of 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 changes to the OPPS in this final rule with comment period will affect both a substantial number of rural hospitals as well as other classes of hospitals and that the effects on some may be significant. Therefore, the Secretary has determined that this final rule with comment period will have a significant impact on the operations of a substantial number of small rural hospitals.

In addition, the Secretary has determined that the final rule on the ASC CfCs will not have a significant impact on the operations of a substantial number of rural hospitals because ASCs are designed to only provide procedures on an outpatient basis, and, thus, are not competing with rural hospitals for inpatient procedures.

Also, the clarification of Medicare termination policy for providers and suppliers, specifically transplant centers, in this final rule will have no significant effect on 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 $130 million. This final rule with comment period will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs. The final rule relating to revisions of the ASC CfCs and the final rule containing policy clarification of the policy on termination of Medicare providers and suppliers will not have an effect on the expenditures of State, local, or tribal government, and the impact on the private sector is estimated to be less than $120 million.

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 final rule with comment period in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication. As reflected in Table 51 below, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) will increase by 4.4 percent under this final rule with comment period. The provisions related to payments to ASCs in CY 2009 will not affect payments to governmental hospitals.

In addition, this final rule on ASC CfCs has no Federalism implications and will not affect State and local governments. However, for purposes of burden estimates, we are unable to accurately determine the number of ASCs that are already compliant with these requirements. Therefore, we have decided to err on the high cost side and apply the derived cost estimates to the total number of ASCs participating in Medicare. In addition, we believe the increased quality initiatives outlined in the regulation should have little or no effect on the benefit cost of ASC services.

We also have examined the policy clarification relating to termination of Medicare providers and suppliers in this final rule in accordance with Executive Order 13132, Federalism, and have determined that it will not have a substantial direct effect on State, local or tribal governments, preempt State law, or otherwise have a Federalism implication.

B. Effects of OPPS Changes in This Final Rule With Comment Period

We are making 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. In addition, we must review the clinical integrity of payment groups and weights at least annually. Accordingly, in this final rule with comment period, we are updating the conversion factor and the wage index adjustment for hospital outpatient services furnished beginning January 1, 2009, as we discuss in sections II.B. and II.C., respectively, of this final rule with comment period. We also are revising the relative APC payment weights using claims data from January 1, 2007, through December 31, 2007, and updated cost report information. We are continuing the payment adjustment for rural SCHs, including EACHs. We are removing two device categories, HCPCS code C1821 (Interspinous process distraction device (implantable)) and HCPCS code L8690 (Auditory osseointegrated device, includes all internal and external components), from pass-through payment status in CY 2009. Finally, we list the 15 drugs and biologicals in Table 23 of this final rule with comment period that we are removing from pass-through payment status for CY 2009.

Under this final rule with comment period, the update change to the conversion factor as provided by statute will increase total OPPS payments by 3.9 percent in CY 2009. The changes to the APC weights, the changes to the wage indices, and the continuation of a payment adjustment for rural SCHs, including EACHs, will not increase OPPS payments because these changes to the OPPS are budget neutral. However, these updates do change the distribution of payments within the budget neutral system as shown in Table 51 below and described in more detail in this section.

1. Alternatives Considered

Alternatives to the changes we are making and the reasons that we have chosen the options are discussed throughout this final rule with comment period. Some of the major issues discussed in this final rule with comment period and the options considered are discussed below.

a. Alternatives Considered for Payment of Multiple Imaging Procedures

We are revising our payment methodology for multiple imaging procedures performed during a single session using the same imaging modality by applying a composite APC payment methodology in CY 2009. We will provide one composite APC payment each time a hospital bills for second and subsequent procedures described by the HCPCS codes in one imaging family on a single date of

service. As discussed in detail in section II.A.2.e.(5) of this final rule with comment period, we are utilizing three imaging families of HCPCS codes based on imaging modality for purposes of this methodology (that is, Ultrasound, CT and CTA, and MRI and MRA). The composite APC methodology for multiple imaging services will result in the creation of the following five new APCs due to the statutory requirement that we differentiate payment for OPPS imaging services provided with and without contrast: 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 considered three alternative CY 2009 payment options for imaging services under the OPPS. The first alternative we considered was to make no change to the existing payment policy of providing hospitals a full APC payment for each imaging service on a claim, regardless of how many procedures are performed during a single session using the same imaging modality or whether the procedures are performed on contiguous body areas. We did not choose this alternative because we believe that continuing the existing payment methodology would neither reflect nor promote the efficiencies hospitals can achieve when they perform multiple imaging procedures during a single session, as demonstrated in CY 2007 claims data and discussed in section II.A.2.e.(5) of this final rule with comment period.

The second alternative we considered was to utilize the 11 families of imaging HCPCS codes applicable under the MPFS multiple imaging discount policy, distinct groups of codes that are based on imaging modality and contiguous body area, in the development of the multiple imaging composite APCs. We did not choose this alternative because, as we discuss in section II.A.2.e.(5) of this final rule with comment period, we believe that the large number of smaller MPFS families are neither appropriate nor necessary for the OPPS. These groups do not correspond to the larger APC groups of services paid under the OPPS, in contrast to the service-specific payment under the MPFS, and would not reflect all efficiencies that may typically be gained in a single imaging session in the hospital outpatient setting of care.

The third alternative we considered and are adopting for CY 2009 is to develop the multiple imaging composite APCs by collapsing the 11 MPFS imaging families into 3 imaging families based solely on imaging modality. We chose this alternative because we believe that the contiguous body area concept that is central to the MPFS imaging families is not necessary to capture potential efficiencies in a hospital outpatient imaging session. As discussed in section II.A.2.e.(5) of this final rule with comment period, we do not expect second and subsequent imaging services of the same modality involving noncontiguous body areas to require certain duplicate facility services. We believe that collapsing the 11 MPFS imaging families into 3 groups for purposes of the OPPS multiple imaging composite payment methodology most accurately reflects how these services are provided in the hospital outpatient setting of care and will most effectively encourage hospital efficiencies that could be achieved when multiple imaging procedures are performed during a single session. We also believe that deriving the multiple imaging composite APCs from 3 collapsed imaging families, rather than the 11 MPFS imaging families, will enable us to maximize the use of multiple imaging claims for ratesetting.

b. Alternatives Considered for the HOP QDRP Requirements for the CY 2009 Payment Update

As discussed in section XVI.D.2. of this final rule with comment period, we are implementing the payment provisions of section 109(a) of the MIEA–TRHCA, which amended section 1833(t) of the Act by adding a new subsection (17). In summary, new section 1833(t)(17)(A) of the Act requires that certain hospitals that fail to meet the HOP QDRP reporting requirements incur a 2.0 percentage point reduction to their OPD fee schedule increase factor, that is, the market basket update. 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 performed by hospitals that are required to report outpatient quality data and that fail to meet the HOP QDRP requirements.

As described in detail in section XVI.D.2. of this final rule with comment period, effective for services paid under the CY 2009 OPPS, we will calculate two conversion factors: A full market basket conversion factor (that is, the full CF) and a reduced market basket conversion factor (that is, the reduced CF). We will calculate a ''reporting ratio'' that will apply to payment for hospitals that fail to meet their reporting requirements, by dividing the reduced CF by the full CF.

Under the OPPS, we have two levels of Medicare beneficiary copayment for many separately paid services: The minimum unadjusted copayment and the national unadjusted copayment. The minimum unadjusted copayment is always 20 percent of the unadjusted national payment rate for each separately payable service. The national unadjusted copayment is determined based on the historic coinsurance rate for the services assigned to the APC. We considered two alternative policy options for the copayment calculation methodology for those hospitals that fail to meet the HOP QDRP requirements.

The first alternative we considered was to calculate the national unadjusted copayments and the minimum unadjusted copayments based on the reduced national unadjusted payment rates, using our standard copayment methodology. We found that, in many cases, the beneficiary copayment amount would remain the same as calculated based on the full national unadjusted payment rates, although the total reduced national unadjusted payment rate would decline because of the reduction to the conversion factor. Therefore, in these cases, the ratio of the copayment to the total payment (the coinsurance percentage) would increase rather than decrease if we were to calculate copayments based on the reduced national unadjusted payment rates. We did not choose this option because we believe that the increased coinsurance percentage that results from this methodology is contradictory to the intent of the statute that the coinsurance percentage should never increase and is also contradictory to our copayment rules that are intended to gradually reduce the percentage of the payment attributed to copayments until the copayment is equal to the minimum unadjusted copayment for all services.

The second alternative we considered and are adopting is to apply the reporting ratio noted above to both the national unadjusted copayment and the minimum unadjusted copayment that would apply to each APC for hospitals that receive the reduced CY 2009 OPPS payment update. Beneficiaries and secondary payers will therefore not pay a higher coinsurance rate and will share in the reduction of payments to these hospitals. We believe that this alternative will allow us to appropriately set the national unadjusted copayments for the reduced OPPS national unadjusted payment rates and is most consistent with the eventual establishment of 20 percent of the payment rate as the uniform

coinsurance percentage for all services under the OPPS.

c. Alternatives Considered Regarding OPPS Cost Estimation for Relative Payment Weights

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. To explore this issue, in August 2006, we awarded a contract to RTI to study the effects of charge compression in calculating the IPPS relative weights, particularly with regard to the impact on inpatient DRG payments, and to consider methods to reduce the variation in the CCRs used to calculate costs for the IPPS relative weights across services within cost centers. Of specific note was analysis of a regression-based methodology estimating an average adjustment for CCRs by type of revenue code from an observed relationship between provider cost center CCRs and proportional billing of high and low cost services in the cost center.

In August 2007, we expanded the RTI contract to determine whether the findings of the report were also applicable to the payment weights established under the OPPS and to more systematically explore cost estimation issues specific to the OPPS, including the revenue code-to-cost center crosswalk. We refer readers to section II.A.1.c. of this final rule with comment period for discussion of the issues and the Web site at *http://www.rti.org* for the RTI findings and recommendations.

The final RTI report describing its research findings was made available at about the time of the issuance of the CY 2009 OPPS/ASC proposed rule. In this report, RTI made a number of recommendations for achieving more accurate estimates of cost for services paid under both the IPPS and the OPPS. This report also distinguished between two types of research findings and recommendations, that is, those pertaining to the accounting or cost report data itself and those related to statistical regression analysis. RTI made 11 recommendations to improve IPPS and OPPS cost estimation, including both short-term and long-term accounting changes, and short-term regression-based and other statistical adjustments. For a detailed discussion of the RTI recommendations from the July 2008 report, we refer readers to section II.A.1.c. of this final rule with comment period.

With respect to adopting the RTI recommendations, we considered three alternatives. The first alternative we considered and the one we adopted was to make no changes in response to the RTI findings and to accept none of the recommendations regarding cost estimation. While we agree with RTI's findings that there are likely misassigned costs in the cost reports that could adversely affect the OPPS relative weights and that charge compression influences the OPPS payment weights, we are adopting this alternative for CY 2009 OPPS for the reasons discussed in detail in the discussion of charge compression in sections II.A.1.c.(2) and V.B.3. of this final rule with comment period. However, as we discussed in the FY 2009 IPPS final rule with comment period (73 FR 48458 through 48467), we believe that creation of a new cost center to facilitate more accurate estimation of device costs is preferable to the regression-based adjustment of CCRs. Moreover, as we explain in section II.A.1.c.(2) of this final rule with comment period, prior to adopting any changes in the revenue code-to-cost center crosswalk used to adjust hospital charges to costs for OPPS ratesetting as recommended by RTI, we will provide a streamlined comparison of median costs that isolates changes attributable to the revenue code-to-cost center crosswalk to allow for informed analysis and additional public input regarding the RTI-recommended changes to the crosswalk.

The second alternative we considered was to accept all of the RTI recommendations. We did not choose this alternative because of the magnitude and scope of impact on APC relative weights that would result from adopting all accounting and statistical changes in cost estimation that were recommended. Further, the numerous and substantial changes that RTI recommended have significantly complex interactions with one another, and we believe that we should proceed cautiously in considering their adoption. In a budget neutral payment system, increases in payment for some services always result in reductions to payment for other services. We believe that any potential accounting and statistical changes in cost estimation are likely to result in significant shifts in payment among hospital departments and among hospitals and should be thoroughly assessed before we decide whether to propose changes in OPPS cost estimation.

The third alternative we considered was to break the single standard cost center 5600 on the Medicare cost report into two new standard cost centers, Drugs with High Overhead Cost Charged to Patients and Drugs with Low Overhead Cost Charged to Patients, to reduce the reallocation of pharmacy overhead cost from expensive to inexpensive drugs and biologicals when setting an equivalent average ASP-based payment amount in the future. As discussed in section V.B.3. of this final rule with comment period, we did not choose this alternative because hospitals indicated that it would be an extraordinary administrative burden to report the HCPCS codes for drugs administered to inpatients that are paid separately under the OPPS (but not paid separately under the IPPS) and to allocate the pharmacy overhead costs (for example, salaries, supplies, and equipment costs) between two new drug cost centers.

2. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the CY 2009 policy changes on various hospital groups. We post on our Web site our hospital-specific estimated payments for CY 2009 with the other supporting documentation for this final rule with comment period. To view the hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/*. Select ''regulations and notices'' from the left side of the page and then select ''CMS–1404–FC'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the other supporting documentation for this final rule with comment period. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 51 below. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A.2. of this final rule with comment period for a discussion of the hospitals whose claims we do not use for ratesetting and impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available, but do not attempt to predict behavioral responses to our policy changes. In addition, we do not make adjustments for future changes in variables such as service volume, service-mix, or number of encounters. As we have done in previous rules, we solicited public comment and information about the anticipated effect of our proposed

changes on hospitals and our methodology for estimating them.

We received several public comments on the form and content of the impact analysis.

Comment: Many commenters stated their concern that no Louisiana CMHCs (including small or rural CMHCs) were included in the impact table. The commenters believed that CMS is required by regulation to calculate the estimated impact of the OPPS/ASC proposed rule on all small and rural providers. Another commenter was concerned with CY 2009 proposed policy changes that the commenter believed would reduce OPPS payments to Michigan hospitals. The commenter estimated that Michigan hospitals would lose approximately $115 million annually when providing OPPS services to Medicare beneficiaries.

Response: We are including estimated impacts for all providers (including small, rural CMHCs located in Louisiana) in the first line of Table 51 in this final rule with comment period. We also are including estimated impacts for all CMHCs on the last line of the impact table. Furthermore, we post on the CMS Web site estimated impact for every hospital and CMHC whose claims were used in modeling the impacts of this final rule with comment period. As noted above, to view the hospital-specific estimates, we refer readers to the CMS Web site at: *http://www.cms.hhs.gov/HospitalOutpatientPPS/.* Select ''regulations and notices'' from the left side of the page and then select ''CMS–1404–FC'' from the list of regulations and notices. Hospitals and CMHCs whose claims were used in ratesetting and modeling the impact of this CY 2009 OPPS/ASC final rule with comment period can review the estimated impact that the policies adopted in this CY 2009 OPPS/ASC final rule with comment period may have on them by looking at our estimates on this table. There are estimated payments for more than 50 CMHCs from Louisiana in the file. With respect to Michigan hospitals, we estimate that 94 percent of the hospitals in Michigan would receive increased OPPS payments as a result of the CY 2009 OPPS.

In summary, we have made available on the CMS Web site the estimated amounts that we expect would be paid to each hospital and CMHC for which claims were used in ratesetting and modeling of impacts for the CY 2009 OPPS. These estimated amounts were used to generate the impacts identified in Table 51 below.

3. Estimated Effects of This Final Rule with Comment Period on Hospitals

Table 51 below shows the estimated impact of this final rule with comment period on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all hospitals, has always included cancer and children's hospitals, which are held harmless to their pre-BBA payment to cost ratio. We also are including CMHCs in the first line that includes all providers because we included CMHCs in our weight scaler estimate. We typically do not report a separate impact for CMHCs because they are paid for only one service, PHP, under the OPPS, and each CMHC can typically easily estimate the impact of the changes by referencing payment for PHP services in Addendum A to this final rule with comment period. Because we are adopting a CY 2009 policy change to PHP payment that is more complicated than a simple change in the payment rate, this year we present separate impacts for CMHCs in Table 51 and discuss the impact on CMHCs in section XXIII.B.4. of this final rule with comment period.

The estimated increase in the total payments made under the OPPS is limited by the increase to the conversion factor set under the methodology in the statute. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The enactment of Public Law 108–173 on December 8, 2003, provided for the additional payment outside of the budget neutrality requirement for wage indices for specific hospitals reclassified under section 508. The MMSEA extended section 508 reclassifications through September 30, 2008. Section 124 of Public Law 110–275 further extended section 508 reclassifications through September 30, 2009. The amounts attributable to this reclassification are incorporated into the CY 2008 estimates.

Table 51 shows the estimated redistribution of hospital and CMHC payments among providers as a result of APC reconfiguration and recalibration; wage indices; the combined impact of the APC recalibration, wage effects, and the market basket update to the conversion factor; and, finally, estimated redistribution considering all payments for CY 2009 relative to all payments for CY 2008, including the impact of changes in the outlier threshold and changes to the pass-through payment estimate. We did not model a budget neutrality adjustment for the rural adjustment for SCHs, including EACHs, because we are not making any changes to the policy for CY 2009. Because updates to the conversion factor, including the update of the market basket and the subtraction of additional money dedicated to pass-through payment for CY 2009, are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services will change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this final rule with comment period will redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2008 and CY 2009, which CMS cannot forecast.

Overall, the final OPPS rates for CY 2009 will have a positive effect for providers paid under the OPPS, resulting in a 3.9 percent increase in Medicare payments. Removing cancer and children's hospitals because their payments are held harmless to the pre-BBA ratio between payment and cost, and CMHCs, suggests that these changes will result in a 4.1 percent increase in Medicare payments to all other hospitals, exclusive of transitional pass-through payments. The majority of the difference is attributable to the redistribution of 0.24 percent of total spending from CMHCs due to the changes in payment for partial hospitalization services. The remainder of the difference is attributable to changes in OPPS payment to cancer and children's hospitals, which are not adversely affected by this estimated reduction in OPPS payment because the law provides additional payment for them that is outside of OPPS budget neutrality.

To illustrate the impact of the final CY 2009 changes, our analysis begins with a baseline simulation model that uses the final CY 2008 weights, the FY 2008 final post-reclassification IPPS wage indices, and the final CY 2008 conversion factor. Column 2 in Table 51 shows the independent effect of changes resulting from the reclassification of services among APC groups and the recalibration of APC weights, based on 12 months of CY 2007 hospital OPPS claims data and more recent cost report data. We modeled the effect of APC recalibration changes for CY 2009 by varying only the weights (the final CY 2008 weights versus the CY 2009 weights calculated using the CY 2007 claims used for this final rule with

comment period) and calculating the percent difference in payments. Column 2 also reflects the effect of changes resulting from the APC reclassification and recalibration changes and any changes in multiple procedure discount patterns that occur as a result of the changes in the relative magnitude of payment weights.

Column 3 reflects the independent effects of updated wage indices, including application of budget neutrality for the rural floor policy on a statewide basis. While we have included changes to the rural adjustment in this column in the past, we did not model a budget neutrality adjustment for the rural adjustment for SCHs, including EACHs, because we are making no changes to the policy for CY 2009. We modeled the independent effect of updating the wage index and the rural adjustment by varying only the wage index, using the CY 2009 scaled weights and a CY 2008 conversion factor that included a budget neutrality adjustment for changes in wage effects and the rural adjustment between CY 2008 and CY 2009.

Column 4 demonstrates the combined ''budget neutral'' impact of APC recalibration (that is, Column 2), the wage index update (that is, Column 3), as well as the impact of updating the conversion factor with the market basket update. We modeled the independent effect of the budget neutrality adjustments and the market basket update by using the weights and wage indices for each year, and using a CY 2008 conversion factor that included the market basket update and budget neutrality adjustments for differences in wages.

Finally, Column 5 depicts the full impact of the CY 2009 policies on each hospital group by including the effect of all the changes for CY 2009 (including the APC reconfiguration and recalibration shown in Column 2) and comparing them to all estimated payments in CY 2008, including changes to the wage index under section 508 of Public Law 108–173 as extended by the MMSEA and further extended by Public Law 110–275. Column 5 shows the combined budget neutral effects of Columns 2 through 4, plus the impact of the change to the fixed outlier threshold from $1,575 to $1,800; the impact of the section 508 reclassification wage index extension; and the impact of increasing the estimate of the percentage of total OPPS payments dedicated to transitional pass-through payments. We estimate that these cumulative changes will increase payments to all providers by 3.9 percent for CY 2009. We modeled the independent effect of all changes in Column 5 using the final weights for CY 2008 and the final weights for CY 2009. We used the final conversion factor for CY 2008 of $63.694 and the CY 2009 conversion factor of $66.059. Column 5 also contains simulated outlier payments for each year. We used the charge inflation factor used in the FY 2009 IPPS final rule of 5.85 percent (1.0585) to increase individual costs on the CY 2007 claims to reflect CY 2008 dollars, and we used the most recent overall CCR in the July 2008 Outpatient Provider-Specific File. Using the CY 2007 claims and a 5.85 percent charge inflation factor, we currently estimate that outlier payments for CY 2008, using a multiple threshold of 1.75 and a fixed-dollar threshold of $1,575, will be approximately 0.73 percent of total payments. Outlier payments of 0.73 percent appear in the CY 2008 comparison in Column 5. We used the same set of claims and a charge inflation factor of 12.04 percent (1.1204) and the CCRs in the July 2008 Outpatient Provider-Specific File, with an adjustment of 0.9920 to reflect relative changes in cost and charge inflation between CY 2007 and CY 2009, to model the CY 2009 outliers at 1.0 percent of total payments using a multiple threshold of 1.75 and a fixed-dollar threshold of $1,800.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 51 shows the total number of providers (4,252), including cancer and children's hospitals and CMHCs for which we were able to use CY 2007 hospital outpatient claims to model CY 2008 and CY 2009 payments by classes of hospitals. We excluded all hospitals for which we could not accurately estimate CY 2008 or CY 2009 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this final rule with comment period. At this time, we are unable to calculate a disproportionate share (DSH) variable for hospitals not participating in the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include psychiatric hospitals, rehabilitation hospitals, and LTCHs. We show the total number (3,970) of OPPS hospitals, excluding the hold-harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to a proportion of their pre-BBA payment relative to their pre-BBA costs and, therefore, we removed them from our impact analyses. We show the isolated impact on 222 CMHCs in the last row of the impact table and discuss that impact separately below.

Column 2: APC Changes Due to Reassignment and Recalibration

This column shows the combined effects of reconfiguration, recalibration, and other policies (such as composite payment for multiple imaging procedures performed on the same day, payment for separately payable drugs at ASP+4 percent, and changes in payment for PHP services). In many cases, the redistribution of 0.24 percent of total OPPS spending created by the reduction in the PHP payment offsets other recalibration losses. Specifically, the reduction in PHP payment is redistributed to hospitals and reflected in the 0.3 percent increase for the 3,970 hospitals that remain after excluding hospitals held harmless and CMHCs. Overall, these changes will increase payments to urban hospitals by 0.3 percent. We estimate that large urban hospitals will see an increase of 0.3 percent and other urban hospitals will see a 0.4 percent increase in payments, all attributable to recalibration.

Overall, rural hospitals will show a 0.1 percent increase as a result of changes to the APC structure. With the money redistributed from PHP services, and other recalibration changes, rural hospitals of all bed sizes will experience no change or will experience changes ranging from −0.5 to 0.6 percent.

Among teaching hospitals, the largest observed impacts resulting from APC recalibration include an increase of 0.5 percent for major teaching hospitals and an increase of 0.4 percent for minor teaching hospitals.

Classifying hospitals by type of ownership suggests that proprietary hospitals will see an increase of 0.2 percent, governmental hospitals will see an increase of 0.2 percent, and voluntary hospitals will see an increase of 0.3 percent.

We note also that both low volume urban and rural hospitals with less than 5,000 lines and hospitals for which DSH payments are not available will experience decreases of 0.3 to 2.5 percent as a result of the decline in payment for PHP services and the change in payment policy for PHP services from one per diem rate in CY 2008 to two per diem rates in CY 2009, as well as other recalibration changes.

Column 3: New Wage Indices and the Effect of the Rural Adjustment

This column estimates the impact of applying the final FY 2009 IPPS wage indices for the CY 2009 OPPS. Overall, these changes will not change the payments to urban or rural hospitals.

Among teaching hospitals, the largest observed impact resulting from changes to the wage indices is a decrease of 0.1 percent for major teaching hospitals in contrast to no change for minor teaching hospitals. Classifying hospitals by type of ownership suggests that governmental hospitals will see an increase of 0.2 percent, and voluntary and proprietary hospitals will experience no change.

We estimate that the combination of updated wage data from FY 2005 cost reports and statewide application of rural floor budget neutrality redistributes payment among regions. Both rural and urban areas in New England and the Middle Atlantic states experience declines of up to 0.8 percent. The Central regions (excluding the East North Central regions) and the Pacific regions of the country experience increases up to 1.2 percent. Change in Puerto Rico's wage data contributes to the decrease of 0.9 percent.

Column 4: All Budget Neutrality Changes and Market Basket Update

The addition of the market basket update of 3.6 percent mitigates any negative impacts on payments for CY 2009 created by the budget neutrality adjustments made in Columns 2 and 3. In general, all hospitals will see an increase of 3.9 percent, attributable to the 3.6 percent market basket increase, the 0.24 percent increase in payment weight created by the reduction in payment for PHP services that is then redistributed to other services and the 0.04 percent redistribution from dedicated cancer and children's hospitals (which are not affected by the redistribution because the law holds them harmless). The 0.28 percent increase is rounded to 0.3 for purposes of Table 51.

Overall, these changes will increase payments to urban hospitals by 3.9 percent. We estimate that large urban hospitals will see an increase of 3.8 percent and other urban hospitals will see a 4.1 percent increase.

Overall, rural hospitals will experience a 3.7 percent increase as a result of the market basket update and other budget neutrality adjustments. Rural hospitals that bill less than 5,000 lines will experience a 3.8 percent increase. Increases in payment due to the wage index modestly offset the reduction in payment for PHP services in low volume rural hospitals. Rural hospitals that bill more than 5,000 lines will experience increases of 2.9 to 3.9 percent.

Among teaching hospitals, the observed impacts resulting from the market basket update and other budget neutrality adjustments include an increase of 4.0 percent for both major and minor teaching hospitals.

Classifying hospitals by type of ownership suggests that proprietary hospitals will increase 3.8 percent, governmental hospitals will increase 4.0 percent, and voluntary hospitals will experience an increase of 3.9 percent.

Column 5: All Changes for CY 2009

Column 5 compares all changes for CY 2009 to final payment for CY 2008 and includes the extended section 508 reclassification wage indices, the change in the outlier threshold, and the difference in pass-through estimates which are not included in the combined percentages shown in Column 4. Overall, we estimate that providers will experience an increase of 3.9 percent under this final rule with comment period in CY 2009 relative to total spending in CY 2008. The projected 3.9 percent increase for all providers in Column 5 reflects the 3.6 percent market basket increase, less 0.02 percent for the change in the pass-through estimate between CY 2008 and CY 2009, plus 0.27 percent for the difference in estimated outlier payments between CY 2008 (0.73 percent) and CY 2009 (1.0 percent), less 0.02 percent for the extended section 508 wage payments, and results in 3.87 percent that rounds to the 3.9 percent increase shown in Table 51. When we exclude cancer and children's hospitals (which are held harmless to their pre-OPPS costs) and CMHCs, the gain will be 4.1 percent.

The combined effect of all changes for CY 2009 will increase payments to urban hospitals by 4.2 percent. We estimate that large urban hospitals will see a 4.1 percent increase, while ''other'' urban hospitals will experience an increase of 4.3 percent. Urban hospitals that bill less than 5,000 lines will experience an increase of 1.4 percent.

Overall, rural hospitals will experience a 3.9 percent increase as a result of the combined effects of all changes for CY 2009. Rural hospitals that bill less than 5,000 lines will experience an increase of 4.6 percent, which is greater than the 3.8 percent increase in Column 4. All rural hospitals that bill greater than 5,000 lines will experience increases ranging from 3.1 percent to 4.1 percent.

Among teaching hospitals, the largest observed impacts resulting from the combined effects of all changes include an increase of 4.5 percent for major teaching hospitals and an increase of 4.2 percent for minor teaching hospitals.

Classifying hospitals by type of ownership suggests that proprietary hospitals will gain 3.9 percent, governmental hospitals will experience an increase of 4.4 percent, and voluntary hospitals will experience an increase of 4.1 percent.

4. Estimated Effects of This Final Rule With Comment Period on CMHCs

The last row of the impact analysis in Table 51 demonstrates the impact on CMHCs. We modeled this impact assuming that CMHCs will continue to provide the same number of days of PHP care, with each day having either three services or four or more services, as seen in the CY 2007 claims data. Using these assumptions, there will be a 22.8 percent decrease in payments to CMHCs due to these APC policy changes (shown in Column 2). Column 3 shows that the CY 2009 wage index updates account for a small decrease in payments to CMHCs (0.3 percent). We note that all providers paid under the OPPS, including CMHCs, receive a 3.6 percent market basket increase (shown in Column 4). Combining this market basket increase, along with changes in APC policy for CY 2009 and the CY 2009 wage index updates, the combined impact on CMHCs for CY 2009 is a 19.5 percent decrease.

We anticipate that CMHCs will change their behavior in response to the CY 2009 payment rates for PHP services, consistent with patient need. By providing one additional qualifying partial hospitalization service, CMHCs will qualify for payment of APC 0173 (Level II Partial Hospitalization payment (4 or more services)), whose payment rate is approximately $205, rather than APC 0172 (Level I Partial Hospitalization payment rate (3 services)), whose payment rate is approximately $161. This change in behavior will lessen the impact on CMHCs in CY 2009.

Using the CY 2007 CMHC claims data, there are a large number of days provided by CMHCs with only 3 services furnished in a given day (approximately 1 million days billed by CMHCs were for 3 units of service). If CMHCs were to provide 1 additional service on 50 percent of those 1 million days with 3 services, we estimate that the impact on CY 2009 payment to CMHCs will be a 15.8 percent decrease rather than a 22.8 percent decrease (which is the decrease due to APC

changes, while keeping the number of days with 3 services the same as reflected in CY 2007 claims data). Continuing to use the assumption that 50 percent of CMHC days with three services would qualify for the Level II PHP payment rate, we estimate that the combined impact including all changes (market basket increase, changes in APC policy for CY 2009, and CY 2009 wage index updates), on CMHCs for CY 2009 will be approximately a 12.1 percent decrease in payment.

We believe that CMHCs may provide additional services on days in excess of the 50 percent of current 3 service days assumed in the scenario described above, behavior which would further mitigate the estimated decrease in payments to CMHCs. Furthermore, we note that there are approximately 40,000 days billed by CMHCs in CY 2007 with only 1 or 2 PHP services. The impact analysis shown in Table 51 is modeled assuming that those days will not receive any payment, in accordance with our policy to deny payment for days with less than three services. However, we anticipate that CMHCs will also change their behavior in response to our policy to deny payment for days with less than three services, to the extent providing additional services is consistent with the plan of care established by each patient's physician. This change in behavior would mitigate modeled payment reductions to CMHCs because additional days with three or more services would qualify for new APC 0172 or new APC 0173.

TABLE 51—IMPACT OF CHANGES FOR CY 2009 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	Number of hospitals	APC recalibration	New wage index and rural adjustment	Comb (cols 2, 3) with market basket update	All changes
	(1)	(2)	(3)	(4)	(5)
ALL PROVIDERS *	4,252	0.0	0.0	3.6	3.9
ALL HOSPITALS (excludes hospitals held harmless and CMHCs)	3,970	0.3	0.0	3.9	4.1
URBAN HOSPITALS	2,970	0.3	0.0	3.9	4.2
LARGE URBAN (GT 1 MILL.)	1,620	0.3	0.0	3.8	4.1
OTHER URBAN (LE 1 MILL.)	1,350	0.4	0.1	4.1	4.3
RURAL HOSPITALS	1,000	0.1	0.0	3.7	3.9
SOLE COMMUNITY * * *	405	0.1	−0.1	3.6	4.0
OTHER RURAL	595	0.0	0.0	3.7	3.8
BEDS (URBAN):					
0–99 BEDS * * *	1,003	0.4	0.0	4.0	4.2
100–199 BEDS	907	0.2	0.0	3.8	3.9
200–299 BEDS	469	0.4	0.2	4.2	4.3
300–499 BEDS	401	0.4	0.0	4.0	4.3
500 + BEDS	190	0.3	−0.2	3.7	4.2
BEDS (RURAL):					
0–49 BEDS * * *	356	−05	0.1	3.2	3.4
50–100 BEDS * * *	379	−0.1	−0.1	3.4	3.6
101–149 BEDS	159	0.0	0.2	3.8	3.9
150–199 BEDS	62	0.4	0.1	4.2	4.4
200 + BEDS	44	0.6	−0.2	4.0	4.4
VOLUME (URBAN):					
LT 5,000 Lines	608	−2.5	0.1	1.2	1.4
5,000–10,999 Lines	176	0.4	−0.1	3.9	4.0
11,000–20,999 Lines	280	0.5	0.2	4.3	4.5
21,000–42,999 Lines	514	0.1	0.1	3.8	3.9
GT 42,999 Lines	1,392	0.4	0.0	4.0	4.2
VOLUME (RURAL):					
LT 5,000 Lines	77	−0.3	0.5	3.8	4.6
5,000–10,999 Lines	100	−0.7	0.2	3.1	3.7
11,000–20,999 Lines	187	−0.7	0.0	2.9	3.1
21,000–42,999 Lines	318	−0.3	0.0	3.3	3.5
GT 42,999 Lines	318	0.3	0.0	3.9	4.1
REGION (URBAN):					
NEW ENGLAND	153	0.4	−0.1	3.9	4.1
MIDDLE ATLANTIC	380	0.4	−0.6	3.4	3.5
SOUTH ATLANTIC	457	0.3	−0.1	3.9	4.0
EAST NORTH CENT	471	0.4	−0.4	3.6	4.1
EAST SOUTH CENT	195	0.2	0.0	3.8	4.0
WEST NORTH CENT	189	0.6	0.5	4.7	4.8
WEST SOUTH CENT	486	0.1	0.1	3.8	4.2
MOUNTAIN	192	0.4	0.1	4.2	4.4
PACIFIC	399	0.1	1.2	4.9	5.0
PUERTO RICO	48	0.1	−0.9	2.8	3.2
REGION (RURAL):					
NEW ENGLAND	24	0.9	−0.8	3.7	3.9
MIDDLE ATLANTIC	68	0.3	−0.3	3.6	3.8
SOUTH ATLANTIC	168	−0.2	0.0	3.4	3.5
EAST NORTH CENT	127	0.2	−0.5	3.3	3.6
EAST SOUTH CENT	179	−0.1	0.3	3.7	3.8
WEST NORTH CENT	114	0.3	0.2	4.2	4.8
WEST SOUTH CENT	210	−0.2	0.4	3.9	4.0

TABLE 51—IMPACT OF CHANGES FOR CY 2009 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM—Continued

	Number of hospitals	APC recalibration	New wage index and rural adjustment	Comb (cols 2, 3) with market basket update	All changes
	(1)	(2)	(3)	(4)	(5)
MOUNTAIN	76	−0.2	−0.2	3.2	3.4
PACIFIC	34	−0.1	1.1	4.6	4.8
TEACHING STATUS:					
NON-TEACHING	2,965	0.2	0.0	3.8	4.0
MINOR	725	0.4	0.0	4.0	4.2
MAJOR	280	0.5	−0.1	4.0	4.5
DSH PATIENT PERCENT:					
0	9	1.9	0.0	5.5	5.5
GT 0–0.10	400	0.5	−0.4	3.8	3.9
0.10–0.16	398	0.4	0.0	4.0	4.3
0.16–0.23	815	0.3	−0.1	3.8	4.0
0.23–0.35	985	0.3	0.2	4.1	4.3
GE 0.35	749	0.1	0.1	3.8	4.2
DSH NOT AVAILABLE * *	614	−2.2	0.2	1.5	1.6
URBAN TEACHING/DSH:					
TEACHING & DSH898	0.4	0.0	4.0	4.3	
TEACHING/NO DSH	0	0.0	0.0	0.0	0.0
NO TEACHING/DSH	1,482	0.3	0.0	3.9	4.0
NO TEACHING/NO DSH	7	1.7	−0.1	5.2	5.2
DSH NOT AVAILABLE * *	583	−2.2	0.2	1.5	1.6
TYPE OF OWNERSHIP:					
VOLUNTARY	2,113	0.3	0.0	3.9	4.1
PROPRIETARY	1,275	0.2	0.0	3.8	3.9
GOVERNMENT	582	0.2	0.2	4.0	4.4
CMHCs	222	−22.8	−0.3	−19.5	−19.5

Column (1) shows total hospitals.

Column (2) shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups and the recalibration of APC weights based on CY 2007 hospital claims data.

Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2009 hospital inpatient wage index. We did not make any changes to the rural adjustment.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the market basket update.

Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adds outlier payments. This column also shows the impact of the extended 508 wage reclassification, which ends September 30, 2009.

* These 4,252 providers include children and cancer hospitals, which are held harmless to pre-BBA payments, and CMHCs.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

*** Section 1833(t)(7)(D) of the Act specifies that rural hospitals with 100 or fewer beds and SCHs with 100 or fewer beds (urban and rural) receive additional payment for covered hospital outpatient services furnished during CY 2009 for which the prospective payment amount is less than the pre-BBA amount. The amount of payment is increased by 85 percent of that difference for CY 2009.

5. Estimated Effect of This Final Rule With Comment Period on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary share of payment will increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For example, for a service assigned to Level IV Needle Biopsy/Aspiration Except Bone Marrow (APC 0037) in the CY 2008 OPPS, the national unadjusted copayment was $228.76, and the minimum unadjusted copayment was $172.95. For CY 2009, the national unadjusted copayment for APC 0037 is $228.76, the same national unadjusted copayment in effect for CY 2008. The minimum unadjusted copayment for APC 0037 is $178.60 or 20 percent of the national unadjusted payment rate for APC 0037 of $892.96 for CY 2009. The minimum unadjusted copayment will rise because the payment rate for APC 0037 will rise for CY 2009. In all cases, the statute limits beneficiary liability for copayment for a service to the hospital inpatient deductible for the applicable year. The CY 2009 hospital inpatient deductible is $1,068.

In order to better understand the impact of changes in copayment on beneficiaries, we modeled the percent change in total copayment liability using CY 2007 claims. We estimate, using the claims of the 4,252 hospitals and CMHCs on which our modeling is based, that total beneficiary liability for copayments will decline by approximately $62 million or, as an overall percentage of total payments, from 24.8 percent in CY 2008 to 23.3 percent in CY 2009. This estimated decline in beneficiary liability is a consequence of the APC recalibration and reconfiguration we are adopting for CY 2009.

6. Conclusion

The changes in this final rule with comment period will affect all classes of hospitals and CMHCs. Some classes of hospitals will experience significant gains and others less significant gains, but all classes of hospitals will experience positive updates in OPPS payments in CY 2009. In general, CMHCs will experience an overall decline of 19.5 percent in payment due to the creation of two APCs for PHP and the recalibration of the payment rates. Table 51 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that results in a 3.9 percent increase in payments for CY 2009, after considering all changes to APC reconfiguration and recalibration, as well as the market basket increase, wage index changes, estimated payment for outliers, and changes to the pass-through payment estimate. The accompanying discussion,

in combination with the rest of this final rule with comment period, constitutes a regulatory impact analysis.

7. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 52, we have prepared an accounting statement showing the CY 2009 estimated hospital OPPS incurred benefit impact associated with the CY 2009 hospital outpatient market basket update shown in this final rule with comment period, based on the 2008 Trustees' Report baseline. All estimated impacts are classified as transfers.

TABLE 52—ACCOUNTING STATEMENT: CY 2009 ESTIMATED HOSPITAL OPPS INCURRED BENEFIT IMPACT ASSOCIATED WITH THE CY 2009 HOSPITAL OUTPATIENT MARKET BASKET UPDATE (IN BILLIONS)

Category	Transfers
Annualized Monetized Transfers	$0.8 billion.
From Whom to Whom	Federal Government to outpatient hospitals and other providers who received payment under the hospital OPPS.
Total	$0.8 billion.

C. Effects of ASC Payment System Changes in This Final Rule With Comment Period

On August 2, 2007, we published in the **Federal Register** the final rule for the revised ASC payment system, effective January 1, 2008 (72 FR 42470). In that final rule, we: Adopted the methodologies to set payment rates for covered ASC services to implement the revised payment system so that it would be designed to result in budget neutrality as required by section 626 of Public Law 108–173; established that the OPPS relative payment weights would be the basis for payment and that we would update the system annually as part of the OPPS rulemaking cycle; and provided that the revised ASC payment rates would be phased-in over 4 years. During the 4-year transition to full implementation of the revised ASC rates, payments for surgical procedures paid in ASCs in CY 2007 will be made using a blend of the CY 2007 ASC payment rate and the revised ASC payment rate for that calendar year. In CY 2009, we are paying ASCs using a 50/50 blend, in which payment would be calculated by adding 50 percent of the CY 2007 ASC rate for a surgical procedure on the CY 2007 ASC list of covered surgical procedures and 50 percent of the CY 2009 revised ASC rate for the same procedure. For CY 2010, we would transition the blend to a 25/75 blend of the CY 2007 ASC rate and the revised ASC payment rate. Beginning in CY 2011, we would pay ASCs for all covered surgical procedures, including those on the CY 2007 ASC list, at the full revised ASC payment rates. Payment for procedures that were not included on the ASC list of covered surgical procedures in CY 2007 is not subject to the transitional payment methodology.

ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XV. of this final rule with comment period, we set the CY 2009 ASC relative payment weights by scaling unadjusted CY 2009 ASC relative payment weights by the ASC scaler of 0.9751. These weights take into consideration the 50/50 blend for the second year of transitional payment for certain services. If there were no transition, the scaler for CY 2009 fully implemented payment rates would be 0.9412. The estimated effects on payment rates during this transitional period are varied and are reflected in the estimated payments displayed in Tables 53 and 54 below.

The CY 2009 ASC conversion factor was calculated by adjusting the CY 2008 ASC conversion factor to account for changes in the pre-floor and pre-reclassified hospital wage indices between CY 2008 and CY 2009. Under section 1833(i)(2)(C)(iv) of the Act, there is no inflation update to the ASC conversion factor for CY 2009. The final CY 2009 ASC conversion factor is $41.393.

1. Alternatives Considered

Alternatives to the changes we are making and the reasons that we have chosen the options are discussed throughout this final rule with comment period.

a. Alternatives Considered for Office-Based Procedures

According to our final policy for the revised ASC payment system, we designate as office-based those procedures that are added to the ASC list of covered surgical procedures in CY 2008 or later years that we determine are usually performed 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. We establish payment for procedures designated as office-based at the lesser of the MPFS nonfacility PE RVU amount or the ASC rate developed according to the standard methodology of the revised ASC payment system.

In developing this final rule with comment period, we reviewed the newly available CY 2007 utilization data for all surgical procedures added to the ASC list of covered surgical procedures in CY 2008 and for those procedures for which the office-based designation is temporary in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66840 through 66841). Based on that review, and as discussed in section XV.E. of this final rule with comment period, we are newly designating eight surgical procedures as office-based, with four of those designations as permanent. We considered two alternatives in developing this policy.

The first alternative we considered was to make no change to the procedure payment designations. This would mean that we would continue to pay for the eight procedures we are designating as office-based at an ASC payment rate developed according to the standard methodology of the revised ASC payment system. We did not select this alternative because our analysis of data for these services and related procedures indicated that the eight procedures we are designating as office-based could be considered to be usually performed in physicians' offices. Consistent with our final policy adopted in the August 2, 2007 revised ASC payment system final rule (72 FR 42509), we were concerned that if these services were not designated as office-based, their ASC payment could create financial incentives for the procedures to shift from physicians' offices to ASCs for reasons unrelated to clinical

decisions regarding the most appropriate setting for surgical care.

The second alternative we considered, and the alternative we selected, is to designate eight additional procedures as office-based for CY 2009. Three of the eight procedures are newly-created CPT codes that will become effective beginning January 1, 2009. We selected this alternative because our review of the most recent available volume and utilization data and/or, if appropriate, the clinical characteristics, utilization and volume of related codes indicated that these procedures could be considered to be usually performed in physicians' offices. We believe that designating these procedures as either temporarily or permanently office-based, which results in the ASC payment rate for these procedures potentially being capped at the physician's office rate (that is, the MPFS nonfacility PE RVU amount), if applicable, is an appropriate step to ensure that Medicare payment policy does not create financial incentives for such procedures to shift unnecessarily from physicians' offices to ASCs, consistent with our final policy adopted in the August 2, 2007 revised ASC payment system final rule.

b. Alternatives Considered for Covered Surgical Procedures

According to our final policy for the revised ASC payment system, we designate as covered surgical procedures all surgical procedures that we determine do not pose a significant risk to beneficiary safety and are not expected to require an overnight stay.

In developing this final rule with comment period, we reviewed the clinical characteristics and newly available CY 2007 utilization data, if applicable, for all procedures reported by Category III CPT codes implemented July 1, 2008, newly created Category I CPT and Level II HCPCS codes for CY 2009, and surgical procedures that were excluded from ASC payment for CY 2008. Based on that review, we identified 16 surgical procedures for which there are newly created Category I CPT codes for CY 2009 CPT and 14 procedures that had been excluded from the list in CY 2008 that meet the criteria for inclusion on the ASC list of covered surgical procedures and we are adding those procedures to the list for CY 2009 payment. We considered two alternatives in developing this policy.

The first alternative we considered was to make no change to the ASC list of covered surgical procedures. We did not select this alternative because our analysis of data for these services and related procedures indicated that the additional 30 procedures we are designating as covered surgical procedures for CY 2009 may be safely provided to beneficiaries in ASCs and are not expected to require an overnight stay. Consistent with our final policy, we were concerned that if these services were not designated as ASC covered surgical procedures, beneficiaries would lack access to these services in the most clinically appropriate setting.

The second alternative we considered, and the alternative we selected, is to designate 30 additional procedures as ASC covered surgical procedures for CY 2009. We selected this alternative because our review of the clinical characteristics and newly available CY 2007 utilization data, if applicable, for all of these procedures indicated that they do not pose a significant risk to beneficiary safety and are not expected to require an overnight stay, and thus they meet the criteria for inclusion on the list of ASC covered surgical procedures. We believe that adding these procedures to the list of covered surgical procedures is an appropriate step to ensure that beneficiary access to services is not limited unnecessarily.

2. Limitations of Our Analysis

Presented here are the projected effects of the changes for CY 2009 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2007 and CY 2009 with precision. The aggregate impacts displayed in Tables 53 and 54 below are based upon a methodology that assumes no changes in service-mix with respect to the CY 2007 ASC data used for this final rule with comment period. In addition, data on services that are newly payable under the revised ASC payment system are not yet reflected in the available claims data. We believe that the net effect on Medicare expenditures resulting from the CY 2009 changes will be negligible in the aggregate. However, such changes may have differential effects across surgical specialty groups as ASCs adjust to payment rates. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs will experience changes in payment that differ from the aggregated estimated impacts presented below.

3. Estimated Effects of This Final Rule With Comment Period on Payments to ASCs

Some ASCs are multispecialty facilities that perform the gamut of surgical procedures, from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect on an individual ASC of the update to the CY 2009 payments will depend on a number of factors including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion presents tables that display estimates of the impact of the CY 2009 update to the revised ASC payment system on Medicare payments to ASCs, assuming the same mix of services as reflected in our CY 2007 claims data. Table 53 depicts the aggregate percent change in payment by surgical specialty group and Table 54 shows a comparison of payment for procedures that we estimate will receive the most Medicare payment in CY 2009.

Table 53 shows the effects on aggregate Medicare payments under the revised ASC payment system by surgical specialty group. We have aggregated the surgical HCPCS codes by specialty group and estimated the effect on aggregated payment for surgical specialty groups, considering separately the CY 2009 transitional rates and the fully implemented revised ASC payment rates that would apply in CY 2009 if there were no transition. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs for CY 2008. The following is an explanation of the information presented in Table 53.

- Column 1—*Surgical Specialty Group* indicates the surgical specialties into which ASC procedures are grouped. We used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.
- Column 2—*Estimated CY 2008 ASC Payments* were calculated using CY 2007 ASC utilization (the most recent full year of ASC utilization) and CY 2008 ASC payment rates. The surgical specialty groups are displayed in descending order based on estimated CY 2008 ASC payments.
- Column 3—*Estimated CY 2009 Percent Change with Transition (50/50 Blend)* is the aggregate percentage increase or decrease, compared to CY 2008, in Medicare program payment to ASCs for each surgical specialty group that is attributable to updates to the ASC payment rates for CY 2009 under the scaled, 50/50 blend of the CY 2007 ASC

payment rate and the CY 2009 ASC payment rate.

• Column 4—*Estimated CY 2009 Percent Change without Transition (Fully Implemented)* is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty group that would be attributable to updates to ASC payment rates for CY 2009 compared to CY 2008 if there were no transition period to the fully implemented payment rates. The percentages appearing in Column 4 are presented only as comparisons to the percentage changes under the transition policy in column 3. We are not eliminating or modifying the policy for a 4-year transition that was finalized in the August 2, 2007 revised ASC payment system final rule (72 FR 42519).

As seen in Table 53, the update to ASC rates for CY 2009 is expected to result in small aggregate decreases in payment amounts for eye and ocular adnexa and nervous system procedures and somewhat greater decreases for digestive system procedures. As shown in column 4 in the table, those payment decreases would be expected to be greater in CY 2009 if there were no transitional payment for all three of those surgical specialty groups.

Generally, for the surgical specialty groups that account for less ASC utilization and spending, the expected payment effects of the CY 2009 update are positive. ASC payments for procedures in those surgical specialties will increase in CY 2009 with the 50/50 transitional payment rates and, in the absence of the transition, would increase even more. For instance, in the aggregate, payment for integumentary system procedures is expected to increase by 7 percent under the CY 2009 rates and by 19 percent if there were no transition. Similar effects are observed for genitourinary, cardiovascular, musculoskeletal, respiratory, and auditory system procedures as well. An estimated increase in aggregate payment for the specialty group does not mean that all procedures in the group will experience increased payment rates. For example, the estimated increased payments at the surgical specialty group level may be due to decreased payments for some of the most frequently provided procedures in the group and the moderating effect of the sometimes substantial payment increases for the less frequently performed procedures within the surgical specialty group.

TABLE 53—ESTIMATED CY 2009 IMPACT OF THE UPDATE TO THE ASC PAYMENT SYSTEM ON ESTIMATED AGGREGATE CY 2009 MEDICARE PROGRAM PAYMENTS UNDER THE 50/50 TRANSITION BLEND AND WITHOUT A TRANSITION, BY SURGICAL SPECIALTY GROUP

Surgical specialty group	Estimated CY 2008 ASC payments (in millions)	Estimated CY 2009 percent change with transition (50/50 blend)	Estimated CY 2009 percent change without transition (fully implemented)
(1)	(2)	(3)	(4)
Eye and ocular adnexa	$1,397	−1	−2
Digestive system	753	−6	−16
Nervous system	327	−3	−10
Musculoskeletal system	222	19	54
Integumentary system	89	7	19
Genitourinary system	88	11	28
Respiratory system	23	14	38
Cardiovascular system	15	16	46
Auditory system	6	25	52

Table 54 below shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected procedures during CY 2009 with and without the transitional blended rate. The table displays 30 of the procedures receiving the greatest estimated CY 2008 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2008 program payment.

• Column 1—*HCPCS code.*

• Column 2—*Short Descriptor* of the HCPCS code.

• Column 3—*Estimated CY 2008 ASC Payments* were calculated using CY 2007 ASC utilization (the most recent full year of ASC utilization) and the CY 2008 ASC payment rates. The estimated CY 2008 payments are expressed in millions of dollars.

• Column 4—*CY 2009 Percent Change with Transition (50/50 Blend)* reflects the percent differences between the estimated ASC payment for CY 2008 and the estimated payment for CY 2009 based on the update, incorporating a 50/50 blend of the CY 2007 ASC payment rate and the CY 2009 revised ASC payment rate.

• Column 5—*CY 2009 Percent Change without Transition (Fully Implemented)* reflects the percent differences between the estimated ASC payment for CY 2008 and the estimated payment for CY 2009 based on the update if there were no transition period to the fully implemented payment rates. The percentages appearing in Column 5 are presented as a comparison to the percentage changes under the transition policy in Column 4. We are not eliminating or modifying the policy for the 4-year transition that was finalized in the August 2, 2007, revised ASC payment system final rule (72 FR 42519).

As displayed in Table 54, 25 of the 30 procedures with the greatest estimated aggregate CY 2008 Medicare payment are included in the three surgical specialty groups that are estimated to account for the most Medicare payment in CY 2008, specifically eye and ocular adnexa, digestive system, and nervous system groups. Consistent with the estimated payment effects on the surgical specialty groups displayed in Table 53, the estimated effects of the CY 2009 update on ASC payment for individual procedures in year 2 of the transition shown in Table 54 are varied. Aggregate ASC payments for many of the most frequently furnished ASC procedures will decrease as the transition causes individual procedure payments to reflect relative ASC payment weights that are more closely

aligned with the relative payment weights under the OPPS.

The ASC procedure for which the most Medicare payment is estimated to be made in CY 2008 is the cataract removal procedure reported with CPT code 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification)). The update to the ASC rates will result in a 1 percent payment decrease for that procedure in CY 2009. The estimated payment effects on the four other high volume eye and ocular adnexa procedures included in Table 54 are slightly positive and negative, but for CPT code 66821 (Discission of secondary membranous cataract (opacified posterior lens capsule and/or anterior hyaloid); laser surgery (e.g., YAG laser) (one or more stages)), the expected CY 2009 payment decrease is 10 percent, significantly greater than the decreases expected for any of the other eye and ocular adnexa procedures shown.

The transitional payment rates for 8 of the 9 digestive system procedures included in Table 54 are expected to decrease by 6 to 9 percent in CY 2009. Those estimated decreases are consistent with the estimated 6 percent reduction shown in Table 53 for the digestive system surgical specialty group.

The 10 nervous system procedures for which the most Medicare payment is estimated to be made to ASCs in CY 2008 are included in Table 54. The CY 2009 update will result in 5 percent payment decreases for 4 of those procedures and result in even more substantial decreases, 19 percent and 22 percent respectively, for CPT code 64484 (Injection, anesthetic agent and/or steroid, transforaminal epidural; lumbar or sacral, each additional level) and CPT code 64476 (Injection, anesthetic agent and/or steroid, paravertebral facet joint or facet joint nerve; lumbar or sacral, each additional level). The other three nervous system procedures included in the table will realize payment increases, especially CPT codes 64622 (Destruction by neurolytic agent, paravertebral facet joint nerve; lumbar or sacral, single level) and 64721 (Neuroplasty and/or transposition; medial nerve at carpal tunnel) for which payment will increase by 13 percent in CY 2009.

The estimated payment effects for most of the remaining procedures listed in Table 54 are positive. For example, the CY 2009 transitional payment rate for CPT codes 29880 (Arthroscopy, knee, surgical; with meniscectomy (medial AND lateral, including any meniscal shaving)) and 29881 (Arthroscopy, knee, surgical; with meniscectomy (medial OR lateral, including any meniscal shaving)) are estimated to increase 17 percent over the CY 2008 transitional payment amount.

TABLE 54—ESTIMATED IMPACT OF UPDATE TO CY 2009 ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

HCPCS code	Short descriptor	Allowed charges (in mil)	Estimated CY 2009 percent change (50/50 Blend)	Estimated CY 2009 percent change without transition (fully implemented)
(1)	(2)	(3)	(4)	(5)
66984	Cataract surg w/iol, 1 stage	1,087	−1	−3
43239	Upper gi endoscopy, biopsy	166	−7	−20
45378	Diagnostic colonoscopy	141	−6	−18
45380	Colonoscopy and biopsy	132	−6	−18
45385	Lesion removal colonoscopy	101	−6	−18
66821	After cataract laser surgery	84	−10	−29
62311	Inject spine l/s (cd)	76	−5	−13
64483	Inj foramen epidural l/s	53	−5	−13
66982	Cataract surgery, complex	51	−1	−3
45384	Lesion remove colonoscopy	38	−6	−18
G0121	Colon ca scrn not hi rsk ind	37	−9	−25
G0105	Colorectal scrn; hi risk ind	32	−9	−25
15823	Revision of upper eyelid	30	4	10
64475	Inj paravertebral l/s	27	−5	−13
43235	Uppr gi endoscopy, diagnosis	24	0	0
52000	Cystoscopy	23	−1	−10
64476	Inj paravertebral l/s add-on	22	−22	−65
29881	Knee arthroscopy/surgery	21	17	49
64721	Carpal tunnel surgery	19	13	38
63650	Implant neuroelectrodes	17	10	20
29880	Knee arthroscopy/surgery	16	17	49
62310	Inject spine c/t	15	−5	−13
67041	Vit for macular pucker	14	0	−3
67904	Repair eyelid defect	14	5	13
64484	Inj foramen epidural add-on	14	−19	−51
43248	Uppr gi endoscopy/guide wire	13	−7	−20
28285	Repair of hammertoe	13	15	41
63685	Insrt/redo spine n generator	12	3	7
64622	Destr paravertebrl nerve l/s	11	13	40
29848	Wrist endoscopy/surgery	11	−4	−12

Predictably, the previous ASC payment system served as an incentive to ASCs to focus on providing procedures for which they determined Medicare payments would support their continued operation. We note that,

historically, the ASC payment rates for many of the most frequently performed procedures in ASCs were similar to the OPPS payment rates for the same procedures. Conversely, procedures with ASC payment rates that were substantially lower than the OPPS rates have been performed least often in ASCs. We believe the revised ASC payment system represents a major stride toward encouraging greater efficiency in ASCs and promoting a significant increase in the breadth of surgical procedures performed in ASCs because it distributes payments across the entire spectrum of covered surgical procedures based on a coherent system of relative payment weights that are related to the clinical and facility resource requirement characteristics of those procedures.

4. Estimated Effects of This Final Rule With Comment Period on Beneficiaries

We estimate that the CY 2009 update to the ASC payment system will be generally positive for beneficiaries with respect to the procedures newly added to the ASC list of covered surgical procedures and for those designated as office-based for CY 2009. First, except for screening colonoscopy and flexible sigmoidoscopy procedures, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment. Second, ASC payment rates under the revised payment system are lower than payment rates for the same procedures under the OPPS, so the beneficiary coinsurance amount under the ASC payment system almost always will be less than the OPPS copayment amount for the same services. (The only exceptions would be if the ASC coinsurance amount exceeds the inpatient deductible. The statute requires that copayment amounts under the OPPS not exceed the inpatient deductible.) For procedures newly added to the ASC list of covered surgical procedures in CY 2009 that migrate from the HOPD to the ASC, the beneficiary coinsurance amount will be less than the OPPS copayment amount. Furthermore, the additions to the list will provide beneficiaries access to more surgical procedures in ASCs. Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the revised ASC payment system, depending on the particular service and the relative payment amounts for that service in the physician's office compared to the ASC. However, for those procedures newly designated as office-based in CY 2009, the beneficiary coinsurance amount will be no greater than the beneficiary coinsurance in the physician's office.

In addition, as finalized in the August 2, 2007 revised ASC payment system final rule (72 FR 42520), in CY 2009, the second year of the 4-year transition to the ASC payment rates calculated according to the standard methodology of the revised ASC payment system, ASC payment rates for a number of commonly furnished ASC procedures will continue to be reduced, resulting in lower beneficiary coinsurance amounts for these ASC services in CY 2009. Continued migration of procedures currently on the list of ASC covered surgical procedures from the HOPD to the ASC will also reduce beneficiary liability for these services, for the two reasons described above with respect to the new ASC covered services.

5. Conclusion

The updates to the ASC payment system for CY 2009 will affect each of the approximately 5,300 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will depend on its mix of patients, the proportion of the ASC's patients that are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the revised payment system, and the extent to which the ASC provides a different set of procedures in the coming year.

The revised ASC payment system is designed to result in the same aggregate amount of Medicare expenditures in CY 2009 as was estimated to be made in CY 2008. We estimate that the update to the revised ASC payment system, including the addition of surgical procedures to the list of covered surgical procedures, that we are adopting for CY 2009 will have no net effect on Medicare expenditures compared to the estimated level of Medicare expenditures in CY 2008.

6. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehousegov/omb/circulars/a004/a-4.pdf*), in Table 55 below, we have prepared an accounting statement showing the classification of the expenditures associated with the statutorily required zero percent update to the CY 2009 revised ASC payment system, based on the provisions of this final rule with comment period. This table provides our best estimate of Medicare payments to providers and suppliers as a result of the update to the CY 2009 ASC payment system, as presented in this final rule with comment period. All expenditures are classified as transfers.

TABLE 55—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM CY 2008 TO CY 2009 AS A RESULT OF THE CY 2009 UPDATE TO THE REVISED ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$0 Million.
From Whom to Whom	Federal Government to Medicare Providers and Suppliers.
Annualized Monetized Transfer	$0 Million.
From Whom to Whom	Premium Payments from Beneficiaries to Federal Government.
Total	$0 Million.

D. Effects of Final Requirements for Hospital Reporting of Quality Data for Annual Hospital Payment Update

1. Hospital Reporting of Outpatient Quality Data Under the HOP QDRP

In section XVII. of the CY 2008 OPPS/ASC final rule with comment period (72 FR 66871), we finalized our measures and requirements for reporting of quality data to CMS for services furnished in hospital outpatient settings under the CY 2009 HOP QDRP. The initial data submission for April to June 2008 services is due to the OPPS Clinical Warehouse by November 1, 2008 (72 FR 66871). CMS and its contractors will provide assistance to all affected hospitals that wish to submit data. In section XVI. of this final rule with comment period, we discuss our measures and requirements for reporting of quality data to CMS for services furnished in hospital outpatient settings under the CY 2010 HOP QDRP.

We have no previous history under the HOP QDRP to indicate the percentage of hospitals that will submit quality data. However, for the initial data submission, in CY 2008, 98 percent of affected hospitals have pledged to participate. In addition, results from the RHQDAPU program indicate that over 98 percent of IPPS hospitals submitted quality data in the initial year of the program. We expect that affected hospitals will participate at approximately the same rate under the HOP QDRP. We have continued our efforts to ensure that our CMS contractors provide assistance to all affected hospitals that wish to submit data. Therefore, for purposes of this CY 2009 impact analysis, we have assumed that the 98 percent of affected hospitals that have pledged to participate will qualify for the full payment update factor for CY 2009.

2. Hospital Reporting of Inpatient Quality Data Under the RHQDAPU Program

In the FY 2009 IPPS proposed rule (73 FR 23651), we noted that, to the extent that the proposed quality measures for FY 2010 under the RHQDAPU program had not already been endorsed by a consensus building entity such as the NQF, we anticipated that they would be endorsed prior to the time that we issued the FY 2009 IPPS final rule. We stated that we intended to finalize the FY 2010 RHQDAPU program measure set for the FY 2010 payment determination in the FY 2009 IPPS final rule, contingent upon the endorsement status of the proposed measures. However, we stated that, if a measure had not received NQF endorsement by the time we issued the FY 2009 IPPS final rule, we intended to finalize that measure for the RHQDAPU program measure set in this CY 2009 OPPS/ASC final rule with comment period if the measure received endorsement prior to the time we issued this CY 2009 OPPS/ASC final rule with comment period (73 FR 23651). We requested public comment on these measures.

In the FY 2009 IPPS final rule (73 FR 48611), we set out, as listed below, two measures which had not yet received NQF endorsement, and that we intended to adopt for the FY 2010 RHQDAPU program measure set in this CY 2009 OPPS/ASC final rule with comment period if the measures receive endorsement from a national consensus-based entity such as NQF:

READMISSION MEASURES (MEDICARE PATIENTS)
• AMI 30-Day Risk Standardized Readmission Measure (Medicare patients).
• Pneumonia (PN) 30-Day Risk Standardized Readmission Measure (Medicare patients).

In section XVI.I. of this final rule with comment period, we finalized these measures because we expect them to receive NQF endorsement. We estimate that the two new RHQDAPU program readmission measures for Medicare patients adopted in this final rule with comment period will have no incremental impact on the percentage of hospitals that will qualify for the full IPPS payment update factor for FY 2010. These two measures are calculated using Medicare Part A inpatient claims already submitted by hospitals. Past experience from adding other RHQDAPU program claims-based measures indicates that no hospitals are expected to be impacted in their FY 2010 IPPS Medicare payment update.

E. Effects of ASC Conditions for Coverage Changes in This Final Rule

1. Effects on ASCs

As described in section XV.B. of the preamble of this document, the ASC CfCs final rule presents new provisions, as well as provisions that are carried over from the existing ASC CfC regulations. For purposes of this section, we have assessed only the impact of the new provisions. Other provisions have not been revised and, therefore, do not present a new burden to ASCs.

Table 56 contains data that are frequently used in this impact statement. The salary-related cost data are referenced from the Salarywizard.com Web site at *http://hrsalarycenter.salary.com.* Some of the requirements contained in the new CfC provisions are already standard medical or business practices. Therefore, these requirements do not present an additional burden to ASCs.

We recognize that, in describing what the effect of this rule will be on ASCs, burden estimates may not accurately reflect the experience of all ASCs. Facilities vary in the complexity of operations and processes, and. therefore, associated costs may differ.

TABLE 56—YEAR 2008 DATA USED THROUGH THIS IMPACT ANALYSIS

Number of Medicare-certified ASCs nationwide	5,100
Average number of patients per ASC	1,240
Hourly rate of administrator*	$49.00
Hourly rate of registered nurse*	$39.00

* Hourly salary rates include base salary, bonuses, Social Security, 401(k)/403(b), disability, health care, pension, and time off.

We are revising the following existing conditions: Governing body and management; Evaluation of quality; and Laboratory and radiologic services. We are finalizing the following new conditions: Patient rights, Infection control, and Patient admission, assessment and discharge.

a. Effects of the Governing Body and Management Provision (§ 416.41)

This ASC CfCs final rule expands the responsibility of the governing body to include the QAPI program and the creation and maintenance of a disaster preparedness plan. The governing body's specific responsibilities for QAPI are detailed in the new QAPI condition located at § 416.43(e). The assignment of burden for this requirement can be found under the description of the QAPI requirement.

The existing regulations require that ASCs meet certain safety requirements under § 416.44, ''Condition for coverage—Environment.'' In an effort to ensure ASCs are equipped to handle emergencies and disasters, we are requiring that ASCs develop a plan specific to disaster preparedness that would provide for the emergency care of patients, ASC staff, and patient family members who are in the ASC when/if unexpected events or circumstances occur at the ASC or in the immediate community that threaten the health of these individuals. The plan requires an ASC to coordinate with appropriate State and local agencies and, as available, to seek their advice on plan development. The plan also requires an annual review to test the plan's effectiveness.

In addition to an annual review, the rule also requires that the ASC staff be able to demonstrate, through annual drills and written evaluations, the ASCs ability to manage emergencies that are likely to occur within their geographic area.

We estimate that an administrator, earning $49.00 per hour, would be largely responsible for developing the plan and for managing the yearly drills and evaluations. We are estimating that the yearly cost for one ASC to develop and implement a disaster preparedness plan will be approximately 4 hours at $49.00 per hour, with a net cost of $196.00 per ASC. The total cost for all ASCs is estimated to be $99,600.

b. Effects of the QAPI Provision (§ 416.43)

In § 416.43, we are replacing the existing requirement, ''Evaluation of quality,'' with a revised requirement entitled, ''Quality assessment and performance improvement''. As part of our efforts to establish regulatory consistency where possible among providers and suppliers, we are adding a QAPI program that requires ASCs to continuously monitor quality improvement through focused projects, identify barriers to improvements, take efforts to measure improvements in patient health outcomes, and work to reduce medical errors. ASCs are also expected to measure, analyze and track quality indicators, including adverse patient events, infection control, and other aspects of performance, including processes of care and services furnished in the ASC.

Once an area of concern is identified, the ASC will develop a plan for improvement. The ASC determines the specifics of the plan, assesses its effectiveness, and monitors the results learned.

This condition includes five standards: program scope; program data; program activities; performance improvement projects; and governing body responsibilities. Because ASCs are already required in the current CfCs to evaluate the quality of care they provide on an ongoing basis, many providers are already using some version of a comprehensive quality assessment and performance improvement program. We estimate that it would take 12 hours for each ASC to develop its own quality assessment performance improvement program. We also estimate that each ASC would spend 18 hours a year collecting and analyzing the findings. In addition, we estimate that each ASC would spend 4 hours a year training its staff and 18 hours a year implementing performance improvement activities. Both the program development and implementation functions would most likely be managed by the ASC's administrator. Based on an hourly rate of $49.00, the total cost of the quality assessment and performance improvement condition for coverage is estimated to be $2,548 per ASC.

The hourly burden is based on estimates that are found in the ''Hospital Conditions of Participation: Quality Assessment and Performance Improvement'' final rule (68 FR 3435, January 24, 2003). We estimated that a hospital would spend 80 hours collecting and analyzing information on 12 identified measures. According to our 2002 statistics, 5,985 hospitals discharged 11.8 million patients in 2000. This means that the statistically average hospital discharged approximately 2,000 patients that year. Collecting and analyzing data for 2,000 patients, we estimate that the implementation burden would take 80 hours. Based on the estimate that the average ASC treats and discharges 1,240 patients per year, we reduced the burden for ASCs to 52 hours each. A new standard, Program scope, requires that the existing evaluation activities demonstrate measurable improvement in patient health outcomes. This rule also requires the use of quality indicator data in the QAPI program, but does not require any specific data collection or utilization, nor would it require ASCs to report the collected data. This would give the ASCs flexibility and minimize burden.

A new standard, Program activities, identifies priority areas that an ASC must consider in its program. ASCs would be expected to carry out assessment activities according to the scope and complexity of their programs.

This rule requires the governing body to become involved in all aspects of the QAPI program. We have estimated the burden based on management by an administrator. There should be direct and open communication between the program manager and the governing body. The analysis of a variety of reports, program prioritization, and allocation of resources are all standard business practices and, therefore, we have not assigned additional burden to these functions.

TABLE 57—SUMMARY OF QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT BURDEN

Standard	Time per ASC (hours)	Total time (hours)	Cost per ASC	Total cost
Developing QAPI	12	61,200	$588	$2,998,800
Collecting/analyzing findings	18	91,800	882	4,498,200
Training staff	4	20,400	196	99,600
Implementing improvement activities	18	91,800	882	4,498,200
Annual total	52	265,200	2,548	12,994,800

The various ASC accreditation and professional health organizations (that is, The Joint Commission, the AAAASF, the AAAHC, and the AOA) support advances in patient care in a number of ways and actively encourage health care entities to expand and improve their existing programs. These organizations are familiar with quality improvement programs and are likely to have actual or referral information available to assist ASCs in setting up their QAPI programs.

In developing a QAPI program, ASCs are urged to take advantage of the variety of information that exists from the industry. ASCs may also find that QAPI programs for other entities, such as hospitals, can be adapted to fit certain needs.

Comment: One commenter disagreed with our estimated costs in the proposed rule of developing and implementing a QAPI program.

Response: In this final rule, we have not increased the burden estimate from the proposed rule because the commenter did not establish cause for a modification.

c. Effects of the Laboratory and Radiologic Services Provision (§ 416.49)

Final changes to this CfC are editorial. There is no additional burden assigned to this CfC.

d. Effects of the Patient Rights Provision (§ 416.50)

The existing regulations do not contain a condition-level patient rights requirement. The final rule recognizes that ASC patients are entitled to certain rights that must be protected and preserved, and that all patients must be free to exercise these rights. The final rule details basic information that ASCs are required to provide to patients: Notice of rights; exercise of patient rights and respect for property and person; privacy and safety; and confidentiality of clinical records. This condition also includes a requirement for advance directives, as specified at 42 CFR Part 489, Subpart I, and a requirement for the submission and investigation of grievances.

We have identified potential burden in the following areas.

(1) Effects of the Notice of Rights—Verbal and Written Notice Provision

An ASC is required to provide patients or, as appropriate, their representatives with verbal or written notice of the rights and responsibilities of the patient in advance of the patient coming under the care of the ASC. Because ASCs must notify patients either verbally or in writing in advance of the patient coming under the ASC's care, ASCs may choose to mail the patient rights notification to the patient along with the pre-surgical information, the physician's financial interests or ownership, and the advance directives. Generally, the most effective and efficient manner to furnish a notice of rights is to initially develop a general notice which can be subsequently discussed and/or distributed as needed. We expect that an ASC will use this simple and inexpensive approach in order to meet this requirement. In response to the needs of their specific patient populations, some ASCs might choose to have their patient rights notification written in the predominant language(s) of their patients. More than likely, this message would be written by a registered nurse or similar professional. A typical message might be in three parts: An introduction; the information section; and a section for followup questions and issues. We expect the effort to develop this one-time message would not exceed 1 hour at a cost of $39.00 for each ASC. We believe that this would be a one-time cost for ASCs and estimate that the total costs would be $198,900 for all ASCs. If an ASC chooses to mail the patient rights to the ASC patient, this form would accompany the other pre-surgical treatment forms that an ASC typically mails to the patient. It is likely that the patient's rights form would consist of a one page, brochure-type informational. We believe the cost associated with adding this informational brochure to the pre-surgical treatment package would be nominal. Therefore, we have not calculated a cost for this mailing.

In many cases, notifying patients verbally of their rights is already being done and some ASCs may already be employing interpreters to make certain that patients who do not understand English fully understand their rights and responsibilities. However, for purposes of this analysis, we will assume that all ASCs need to budget for this activity. The cost for language services can range from moderate hourly amounts to daily, full-time interpreters at $800 per day. Telephonic services are more reasonable and more accessible and can be purchased for $2.00 per minute. We are not able to determine the percentage of non-English speaking patients an ASC would care for in a year as that depends on a number of variables, including the ASC's geographic location. In addition, the availability of in-person language services would also vary from location to location and, while it may not be preferred, in some cases the use of family members may be necessary.

Given this discussion, we estimate that 3 percent of an average annual ASC caseload of 1,240 cases might require interpreter services and 15 minutes of time would be needed for an interpreter to provide a general description of the rights to which the patient is entitled. Because a percentage of an ASC's patients will speak Spanish or French, as these languages are commonly spoken in some parts of the country, we expect that friends and relatives of patients speaking these languages would be available to assist in understanding issues related to the patient's scheduled procedure. Therefore, the need for an ASC to hire an interpreter in these cases would be infrequent. (Other than English, Spanish is the language most commonly spoken in 42 States.) The ASC may have to take steps to arrange for an interpreter for some patients when other options are not available.

- Telephone interpretive services at $2.00/minute × 15 minutes = $30.00 per patient. The cost for telephone interpreter services is, for example, dependent upon the language, the consumed time, or frequency. Costs range from $75.00 an hour to $160.00 or more an hour. The figure of $2.00 per minute is an estimated average cost.
- 3 percent × 1,240 patient caseload = 37 patients per year per ASC requiring the services of an interpreter.
- $30.00 × 37 = $1,110.00 per ASC.
- $1,110 × 5,100 ASCs = $5,661,000 estimated cost total for all ASCs.

(2) Effects of the Advance Directives Provision

Each ASC is required to establish an advance directive policy, and provide the patient or representative with information concerning its policies on advance directives, including a description of applicable State laws and, if requested, official State advance directive forms. Each ASC is also required to explain these policies to their patients. This includes providing information on any conscience objections the physician(s) and/or the ASC might have to advance directives; documenting whether an individual has executed an advance directive; and educating staff on the importance of advance directives. We expect that many ASCs already communicate information about advance directives to their patients because advance directives are common in hospitals and a significant portion of Medicare patients have had some experience with hospitals. Many ASCs have already formulated some type of advance directives policy.

We estimate that the development of an advance directives document utilizing generic advance directives forms obtained from existing Web sites or from State agency Web sites, by a registered nurse or equivalent will take 1 hour at $39.00 per ASC. The estimated cost for all ASCs is $198,900. We randomly queried a small sample of State Web sites and found generic advance directives forms in English and Spanish that were posted and available for downloading.

We believe that these functions reflect standard industry practice and, therefore, would add no burden. While this requirement is subject to the PRA, we believe the burden associated with this requirement would constitute a usual and customary business practice. Pursuant to 5 CFR 1320.3(b)(2), we will not include the cost of this activity in the economic impact analysis.

Some ASCs will choose to mail advance directives to their patients along with the other pre-surgical treatment information. In instances when ASCs mail the advance directives, it would also be appropriate to mail the ASC's disclosures concerning any policies the ASC or the ASC's physicians might have regarding specific patient rights, for example, do not resuscitate orders, etc. We believe such information should be mailed with the package of information in an effort to afford patient the opportunity to seek

out another ASC in the event they are uncomfortable or in disagreement with the ASC's policies on advance directives.

Most advance directives consist of a one-page brochure. Because ASCs already mail a package of information to the patient, we again believe the cost of including a second additional page would be nominal and, therefore, assign no burden to this activity.

(3) Effects of the Submission and Investigation of Patient Complaints Provision

We estimate that an ASC may have to investigate complaints from approximately 1 percent (12 patients) of its caseload due to allegations of mistreatment, and neglect, for example. We are not aware of an existing repository of records that accurately identifies the number and exact nature of ASC complaints. Therefore, 1 percent is an estimate.

An investigation could average 1 hour and would be managed by an administrator. Twelve hours could be spent by each ASC in this activity.

- 12 hours × $49.00 (administrator's hourly salary) = $588 estimated cost for each ASC.
- $588 × 5,100 ASCs = $2,998,800 estimated cost for all ASCs.

In its resolution of the grievance, an ASC must investigate all allegations, document how the violation or grievance was addressed, and provide the patient with written notice of its decision containing the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.

The burden associated with this requirement is the time and effort necessary to fully document the alleged violation or complaint and to disclose the written notice to each patient who filed a grievance. We estimate that, on average, it will take each ASC 15 minutes at a cost of $39.00 an hour to develop and disseminate 12 notices on an annual basis (3 hours per ASC), for a total ASC burden of 15,300 hours at a cost $596,700.

While this requirement is subject to the PRA, we believe it would constitute a usual and customary business practice. Pursuant to 5 CFR 1320.3(b)(2), we will not include this activity in the economic impact analysis.

(4) Effects of the Exercise of Rights and Respect for Property and Person Provision

Since ASCs began operating under Medicare in 1982, they have been required to provide information to patients about the procedures to be performed. This information is provided to patients by way of the informed patient consent in the current regulation. ASCs are also responsible for providing patients with information concerning expected outcomes. The final rule requires that ASCs continue this practice. Therefore, we do not anticipate that ASCs will incur significant costs associated with this requirement.

(5) Effects of the Privacy and Safety Provision

The current regulatory language requires that an ASC provide a safe and sanitary environment to protect the health and safety of patients. The final rule adds the requirement that the patient has the right to personal privacy. We are defining personal privacy in this case as providing the patient access to an area of the ASC which is shielded from view from others to prepare for the procedure to be performed. This would mean a place to disrobe, speak with ASC personnel about issues and concerns, and then get dressed following the procedure. While this requirement is subject to the PRA, we believe that it would constitute a usual and customary business practice. Pursuant to 5 CFR 1320.3(b)(2), we will not include this activity in the economic impact analysis.

(6) Effects of the Confidentiality of Clinical Records Provision

The existing regulation at § 416.47(a) requires that an ASC develop a system for the proper collection, storage, and use of patient records. This use includes such purposes as to provide appropriate health care, for payment information, for disease management, and for quality assessment. The changes in the final rule merely provide a formal clarification of the current requirement's approach the proper use of records. ASCs recognize the need for privacy regarding patient medical records and have already instituted policies based on the Federal HIPAA Privacy Rule, which requires appropriate safeguards to protect the privacy of individually identifiable health information and regulates the use and disclosure of such information. In addition, 48 States have medical privacy laws that are applicable to patients' health information. Some State laws are specific in prohibiting unlawful disclosure of patient information while, in other States, prohibitions are linked to laws governing specific medical entities. Most health care facilities have already instituted procedures to address this issue to conform to State laws. Therefore, we do not believe this final rule will impose any significant additional financial or resource burdens on ASCs.

e. Effects of the Infection Control Provision (§ 416.51)

As we proposed, we are elevating the level of importance of the infection control requirements, located at § 416.44(a)(3), to the condition level. The ASC is required to ensure that the infection control program minimizes infections and communicable diseases that could affect both patients and ASC staff. We are also requiring that a designated professional in the ASC be responsible for the program. We estimate the burden increase to be minimal, except for the ongoing training expense to make certain that the designated professional continues to be familiar with current infection control information.

ASCs are currently required to have a program that identifies and prevents infections, maintains a sanitary environment, and reports results to the appropriate authorities. The new condition requires the ASC to designate an individual (in most cases this would be a nurse or an environmental engineer) to be responsible for the ASC infection control program. The ASC can continue to designate the individual that currently oversees the infection control program. However, the ASC must also assure that the person who is designated is, through a combination of training, knowledge and experience, capable of performing this task. To ensure the individual continues his/her current knowledge of infection control methodologies and techniques, he/she would need to engage in continuing education in infection control on a frequent or at least an annual basis.

We estimate that an ASC would spend approximately $500 per calendar year on infection control training for the designated individual. This cost was based on the quantity of technical information that we believe is appropriate to be included in an infection control program. The cost also includes the time spent by the ASC infection control officer (the trainee), the cost for a qualified trainer and the training materials. We estimate that the course would run 4 hours. The total estimated cost for all ASCs would be $2,550,000. We do not expect that individuals would have to travel any significant distance to meet this training requirement.

Comment: One commenter suggested that CMS underestimated the burden of costs in the proposed rule with respect to the infection control program. The

commenter suggested that the cost estimate for training did not consider the cost associated with initial training.

Response: The existing ASC regulations at § 416.44(a)(3) already requires an ASC to have an infection control program that is capable of identifying and preventing infections. ASC clinicians such as nurses and pharmacists, in addition to physicians, are already involved in implementing infection control practices as part of the current requirement. These professionals already have a fundamental knowledge base from which to draw, and, therefore, we do not believe initial training cost is an issue here. Therefore, we are retaining the burden estimate as proposed.

The infection control condition also includes the requirement that the infection control program be part of the ASC's QAPI program. We have not prescribed specific areas to be monitored or a process that must be followed to meet the requirement. We have not assigned any burden to this requirement because, under the current rules, the ASC should already be evaluating quality activities and executing an infection control program. This requirement has been included as a formal way of ensuring it is an integral part of the ASC's QAPI process.

This CfC requires an ASC to continue to take specific and appropriate actions to address the prevention and control of infections. We do not believe this will add any regulatory burden because this condition reflects contemporary standard practice in ASC facilities and, again, should be part of the ASC obligation under the current rules.

f. Effects of the Patient Admission, Assessment, and Discharge Provision (§ 416.52)

The condition reflects a more patient-centered approach that we believe will result in an improved quality of care, and more emphasis on patient outcomes. Specifically, we are finalizing this new condition because it represents the current standard of practice and does not pose additional burden.

(1) Effects of the Admission and Pre-Surgical Assessment Provision

We are requiring the completion of a comprehensive medical history and physical assessment no more than 30 days before the day of the scheduled surgery. It is very unlikely that the comprehensive medical history will be completed at the ASC. Therefore, there is unlikely to be any ASC burden associated with this requirement.

We are requiring that a pre-surgical assessment be completed upon admission to the ASC. Existing regulations at § 416.42(a) require a physician to examine the patient immediately before surgery to evaluate the risks involved in administering anesthesia and performing the procedure. Physicians must determine that patients, including those at high risk, are able to undergo the surgery itself and be able to manage recovery. Pre-surgical assessments represent a current standard of community practice, are currently required under a different description, and, therefore, do not pose additional burden.

To ensure the ASC health care team has all patient information available when needed, the medical history and physical assessment must be placed in the patient's medical record before the surgical procedure is started. There is no burden associated with this requirement.

(2) Effects of the Post-Surgical Assessment Provision

The post-surgical assessment requires the ASC to ensure the patient's post-surgical condition is documented in the medical record by a physician or other qualified practitioner in accordance with State law and ASC policy, and the patient's post-surgical needs addressed and included in the discharge notes. Post-surgical assessments, located in the current regulation under surgical services, reflect ASC standard of practice, and therefore, do not pose additional burden.

(3) Effects of the Discharge Provision

The ASC is required to provide each patient with discharge instructions and ensure each patient has a signed discharge order, any needed overnight supplies and physician contact information for followup care or an appointment. Requiring the patient to have a signed discharge order, discharge instructions, any immediate overnight supplies that may be needed, and physician contact information when the patient leaves the ASC is standard practice. Therefore, we do not believe this is a new burden for ASCs.

The total compliance cost for ASCs is listed below by condition.

TOTAL COST TO ASCS TO IMPLEMENT REGULATION

Condition	Activity	Cost for all ASCs
§ 416.41	Governing Body (Disaster Preparedness)	$999,600
§ 416.43	QAPI	12,994,800
	Develop Program	($2,998,800)
	Collecting & Analyzing Findings	($4,498,200)
	Training Staff	($ 999,600)
	Implementing Improvement Activities	($4,498,200)
§ 416.50	Patient Rights	9,654,400
	Develop Patient Notice of Rights	($198,900)
	Telephone Interpreter	($5,661,000)
	Develop Advance Directive	($198,900)
	Investigating Patients' Complaints	($2,998,800)
	Develop/Disseminate Complaint Investigation Notice	($ 596,700)
§ 416.51	Annual Infection Control Training	2,550,000
Total Implementation Cost for All ASCs		26,198,800

2. Alternatives Considered

One alternative was to maintain the existing CfCs without revisions. However, we concluded this was not a reasonable option because our existing CfCs, in some cases, are not compatible with the current standards of practice. Revising the existing CfCs takes advantage of continuing advances in the health care delivery field. In addition, listed below are other alternatives.

a. Alternatives to the Governing Body and Management Provision (§ 416.41)

We considered not including the requirement for the disaster preparedness plan. However, as witnessed by the problems affecting health care facilities across the Gulf region in September 2005 as a result of Hurricane Katrina, we have finalized this requirement to ensure the safety of patients and staff members alike.

b. Alternatives to the QAPI Provision (§ 416.43)

We discussed eliminating any reference to the use of quality indicator data, including patient care data. However, in light of the existing and proposed hospital, home health and rural health clinic quality assessment and performance improvement requirements, we believe ASCs also must continue current efforts in quality improvement by building a foundation where quality indicator data can be used to identify activities that lead to poor patient outcomes.

c. Alternatives to the Patient Rights Provision (§ 416.50)

We considered not requiring a patient rights standard in ASCs because we are aware that ASCs currently participate in some patient rights' activities, for example, documenting patient's executed informed consent; safeguarding patient's privacy; and encouraging patients to participate in treatment decisions by discussing treatment options with them. However, to facilitate greater communication between patients and health care facilities and to ensure that patients receive considerate, respectful care in all health care settings, we have determined that ASC facilities should be required to provide patients or their representatives with a notice of the patient's rights in a language that the patient understands. We believe this requirement will protect and promote considerate and respectful treatment of ASC patients.

d. Alternatives to the Discharge Provision (§ 416.52)

We considered requiring that the ASC have a physician on its premises whenever a patient is in the facility. However, we determined this might be impractical considering there are circumstances when patients are present in the ASC facility before and after procedures that do not warrant the need for physician coverage. Therefore, we believe the requirement of a signed discharge order will provide more flexibility and continue to ensure proper physician or qualified provider coverage until the patient has completely recovered and physically leaves the ASC facility.

3. Conclusion

This is not a major rule, because the overall impact for all new conditions is estimated to be $26.2 million annually. Moreover, a detailed assessment of the associated costs and benefits, as outlined by section 202 of the Unfunded Mandates Reform Act, will not be performed because the impact of this regulation does not reach the $130 million threshold.

F. Executive Order 12866

In accordance with the provisions of Executive Order 12866, this OPPS/ASC final rule with comment period, the ASC CfCs final rule, and the final rule that clarifies Medicare policy regarding terminations of providers and suppliers were reviewed by the OMB.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

■ For reasons stated in the preamble of this document, the Centers for Medicare & Medicaid Services is amending 42 CFR Chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for Part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 410.43 is amended by—

■ a. Removing the word ''and'' at the end of paragraph (a)(2).

■ b. Redesignating paragraph (a)(3) as paragraph (a)(4).

■ c. Adding a new paragraph (a)(3).

■ d. Adding a new paragraph (c).

The additions read as follows:

§ 410.43 Partial hospitalization services: Conditions and exclusions.

(a) * * *

(3) Are furnished in accordance with a physician certification and plan of care as specified under § 424.24(e) of this chapter; and

* * * * *

(c) Partial hospitalization programs are intended for patients who—

(1) Require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care;

(2) Are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment;

(3) Do not require 24-hour care;

(4) Have an adequate support system while not actively engaged in the program;

(5) Have a mental health diagnosis;

(6) Are not judged to be dangerous to self or others; and

(7) Have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the partial hospitalization program.

PART 416—AMBULATORY SURGICAL SERVICES

■ 3. The authority citation for Part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 4. Section 416.2 is amended by revising the definition of ''Ambulatory surgical center or ASC'' to read as follows:

§ 416.2 Definitions.

* * * * *

Ambulatory surgical center or *ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC, and must meet the conditions set forth in subparts B and C of this part.

* * * * *

■ 5. Section 416.41 is revised to read as follows:

§ 416.41 Condition for coverage—Governing body and management.

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality

health care in a safe environment, and develops and maintains a disaster preparedness plan.

(a) *Standard: Contract services.* When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.

(b) *Standard: Hospitalization.* (1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.

(2) This hospital must be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter.

(3) The ASC must—

(i) Have a written transfer agreement with a hospital that meets the requirements of paragraph (b)(2) of this section; or

(ii) Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of paragraph (b)(2) of this section.

(c) *Standard: Disaster preparedness plan.* (1) The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC.

(2) The ASC coordinates the plan with State and local authorities, as appropriate.

(3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.

■ 6. Section 416.42 is amended by—

■ a. Revising paragraph (a).

■ b. Removing paragraph (c).

■ c. Redesignating paragraph (d) as paragraph (c).

Revised paragraph (a) reads as follows:

§ 416.42 Condition for coverage—Surgical services.

(a) *Standard: Anesthetic risk and evaluation.* (1) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

(2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at § 410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery.

* * * * *

■ 7. Section 416.43 is revised to read as follows:

§ 416.43 Conditions for coverage—Quality assessment and performance improvement.

The ASC must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.

(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.

(b) *Standard: Program data.* (1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.

(2) The ASC must use the data collected to—

(i) Monitor the effectiveness and safety of its services, and quality of its care.

(ii) Identify opportunities that could lead to improvements and changes in its patient care.

(c) *Standard: Program activities.* (1) The ASC must set priorities for its performance improvement activities that—

(i) Focus on high risk, high volume, and problem-prone areas.

(ii) Consider incidence, prevalence, and severity of problems in those areas.

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.

(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.

(d) *Standard: Performance improvement projects.* (1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.

(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results.

(e) *Standard: Governing body responsibilities.* The governing body must ensure that the QAPI program—

(1) Is defined, implemented, and maintained by the ASC.

(2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.

(3) Specifies data collection methods, frequency, and details.

(4) Clearly establishes its expectations for safety.

(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

■ 8. Section 416.49 is revised to read as follows:

§ 416.49 Condition for coverage—Laboratory and radiologic services.

(a) *Standard: Laboratory services.* If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with Part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of Part 493 of this chapter.

(b) *Standard: Radiologic services.* (1) The ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients.

(2) Radiologic services must meet the hospital conditions of participation for radiologic services specified in § 482.26 of this chapter.

■ 9. A new § 416.50 is added to read as follows:

§ 416.50 Condition for coverage—Patient rights.

The ASC must inform the patient or the patient's representative of the patient's rights, and must protect and promote the exercise of such rights.

(a) *Standard: Notice of rights.* (1) The ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights in advance of the date of the procedure, in a language and manner that the patient or the patient's representative understands. In addition, the ASC must—

(i) Post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or

their representative, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.

(ii) The ASC must also disclose, where applicable, physician financial interests or ownership in the ASC facility in accordance with the intent of Part 420 of this subchapter. Disclosure of information must be in writing and furnished to the patient in advance of the date of the procedure.

(2) *Standard: Advance directives.* The ASC must comply with the following requirements:

(i) Provide the patient or, as appropriate, the patient's representative in advance of the date of the procedure, with information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.

(ii) Inform the patient or, as appropriate, the patient's representative of the patient's right to make informed decisions regarding the patient's care.

(iii) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.

(3) *Standard: Submission and investigation of grievances.* (i) The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC.

(ii) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual, or physical abuse, must be fully documented.

(iii) All allegations must be immediately reported to a person in authority in the ASC.

(iv) Only substantiated allegations must be reported to the State authority or the local authority, or both.

(v) The grievance process must specify timeframes for review of the grievance and the provisions of a response.

(vi) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished.

(vii) The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.

(b) *Standard: Exercise of rights and respect for property and person.*

(1) The patient has the right to—

(i) Exercise his or her rights without being subjected to discrimination or reprisal.

(ii) Voice grievances regarding treatment or care that is (or fails to be) furnished.

(iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed.

(2) If a patient is adjudged incompetent under applicable State health and safety laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.

(3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.

(c) *Standard: Privacy and safety.* The patient has the right to—

(1) Personal privacy.

(2) Receive care in a safe setting.

(3) Be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of clinical records.* The ASC must comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR parts 160 and 164.

■ 10. A new § 416.51 is added to read as follows:

§ 416.51 Conditions for coverage—Infection control.

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

(a) *Standard: Sanitary environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

(b) *Standard: Infection control program.* The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. The program is—

(1) Under the direction of a designated and qualified professional who has training in infection control;

(2) An integral part of the ASC's quality assessment and performance improvement program; and

(3) Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.

■ 11. A new § 416.52 is added to read as follows:

§ 416.52 Conditions for coverage—Patient admission, assessment and discharge.

The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.

(a) *Standard: Admission and pre-surgical assessment.* (1) Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals.

(3) The patient's medical history and physical assessment must be placed in the patient's medical record prior to the surgical procedure.

(b) *Standard: Post-surgical assessment.* (1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(2) Post-surgical needs must be addressed and included in the discharge notes.

(c) *Standard: Discharge.* The ASC must—

(1) Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a followup appointment with the physician, and ensure that all patients

are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for followup care.

(2) Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 12. The authority citation for Part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

■ 13. Section 419.41 is amended by revising paragraph (c)(4)(iv) to read as follows:

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

* * * * *

(c) * * *

(4) * * *

(iv) The copayment amount is computed as if the adjustment under §§ 419.43(d) and (e) (and any adjustments made under § 419.43(f) in relation to these adjustments) and § 419.43(h) had not been paid.

* * * * *

■ 14. Section 419.42 is amended by revising paragraph (e) to read as follows:

§ 419.42 Hospital election to reduce coinsurance.

* * * * *

(e) In electing reduced coinsurance, a hospital may elect a copayment amount that is less than that year's wage-adjusted copayment amount for the group but not less than 20 percent of the APC payment rate as determined under § 419.32 or, in the case of payments calculated under § 419.43(h), not less than 20 percent of the APC payment rate as determined under § 419.43(h).

* * * * *

■ 15. Section 419.43 is amended by—

■ a. In paragraph (d)(1)(i)(B), removing the phrase ''paragraph (e) of this section'' and adding in its place the cross-reference ''§ 419.66''.

■ b. Adding new paragraphs (d)(5) and (d)(6).

■ c. Revising paragraph (f).

■ d. Revising paragraph (g)(4).

■ e. Adding a new paragraph (h)(4).

The additions and revisions read as follows:

§ 419.43 Adjustments to national program payment and beneficiary copayment amounts.

* * * * *

(d) * * *

(5) *Cost-to-charge ratios for calculating charges adjusted to cost.* For hospital outpatient services (or groups of services) as defined in paragraph (d)(1) of this section performed on or after January 1, 2009—

(i) CMS may specify an alternative to the overall ancillary cost-to-charge ratio otherwise applicable under paragraph (d)(5)(ii) of this section. A hospital may also request that its Medicare contractor use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. Such a request must be approved by the CMS.

(ii) The overall ancillary cost-to-charge ratio applied at the time a claim is processed is based on either the most recent settled cost report or the most recent tentative settled cost report, whichever is from the latest cost reporting period.

(iii) The Medicare contractor may use a statewide average cost-to-charge ratio if it is unable to determine an accurate overall ancillary cost-to-charge ratio for a hospital in one of the following circumstances:

(A) A new hospital that has not yet submitted its first Medicare cost report. (For purposes of this paragraph, a new hospital is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18 of this chapter.)

(B) A hospital whose overall ancillary cost-to-charge ratio is in excess of 3 standard deviations above the corresponding national geometric mean. This mean is recalculated annually by CMS and published in the annual notice of prospective payment rates issued in accordance with § 419.50(a).

(C) Any other hospital for whom accurate data to calculate an overall ancillary cost-to-charge ratio are not available to the Medicare contractor.

(6) *Reconciliation.* For hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2009—

(i) Any reconciliation of outlier payments will be based on an overall ancillary cost-to-charge ratio calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the service is settled.

(ii) At the time of any reconciliation under paragraph (d)(6)(i) of this section, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment will be based on a widely available index to be established in advance by CMS, and will be applied from the midpoint of the cost reporting period to the date of reconciliation.

* * * * *

(f) *Excluded services and groups.* The following services or groups are excluded from qualification for the payment adjustment under paragraph (d)(1) of this section:

(1) Drugs and biologicals that are paid under a separate APC; and

(2) Items and services paid at charges adjusted to costs by application of a hospital-specific cost-to-charge ratio.

(g) * * *

(4) *Excluded services and groups.* The following services or groups are excluded from qualification for the payment adjustment in paragraph (g)(2) of this section:

(i) Drugs and biologicals that are paid under a separate APC;

(ii) Devices paid under 419.66; and

(iii) Items and services paid at charges adjusted to costs by application of a hospital-specific cost-to-charge ratio.

* * * * *

(h) * * *

(4) *Beneficiary copayment.* The beneficiary copayment for services to which the adjustment to the conversion factor specified under paragraph (h)(1) of this section applies is the product of the national beneficiary copayment amount calculated under § 419.41 and the ratio of the adjusted conversion factor calculated under paragraph (h)(1) of this section divided by the conversion factor specified under § 419.32(b)(1).

■ 16. Section 419.70 is amended by—

■ a. Revising the introductory text of paragraph (d)(2).

■ b. Revising the heading of paragraph (d)(4).

■ c. Adding a new paragraph (d)(5).

■ d. In paragraphs (e), (g), and (i), removing the term ''paragraph'' and adding it its place the term ''section.''

The revisions and additions read as follows:

§ 419.70 Transitional adjustments to limit decline in payments.

* * * * *

(d) * * *

(2) *Temporary treatment for small rural hospitals on or after January 1, 2006.* For covered hospital outpatient services furnished in a calendar year from January 1, 2006, through December

31, 2009, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 95 percent of that difference for services furnished during 2006, 90 percent of that difference for services furnished during 2007, and 85 percent of that difference for services furnished during 2008 and 2009 if the hospital—

* * * * *

(4) *Temporary treatment for sole community hospitals located in rural areas for covered hospital outpatient services furnished during cost reporting periods beginning on or after January 1, 2004 and before January 1, 2006.* * * *

(5) *Temporary treatment for sole community hospitals located in rural areas on or after January 1, 2009, and through December 31, 2009.* For covered hospital outpatient services furnished on or after January 1, 2009, and continuing through December 31, 2009, for which the prospective payment system amount is less than the pre-BBA amount, the amount of payment under this part is increased by 85 percent of that difference if the hospital—

(i) Is a sole community hospital as defined in § 412.92 of this chapter or is an essential access community hospital as described under § 412.109 of this chapter; and

(ii) Has 100 or fewer beds as defined in § 412.105(b) of this chapter.

* * * * *

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

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: *October 23, 2008.*

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: *October 29, 2008.*

Michael O. Leavitt,

Secretary.

BILLING CODE 4120–01–P

Editorial Note: The following Addenda will not appear in the Code of Federal Regulations.

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0001	Level I Photochemotherapy	S	0 5101	$33.70	$7.00	$6.74
0002	Fine Needle Biopsy/Aspiration	T	1 4324	$94.62		$18.93
0003	Bone Marrow Biopsy/Aspiration	T	3.1527	$208.26		$41.66
0004	Level I Needle Biopsy/ Aspiration Except Bone Marrow	T	4.4727	$295.46		$59.10
0005	Level II Needle Biopsy/Aspiration Except Bone Marrow	T	7.3879	$488.04		$97.61
0006	Level I Incision & Drainage	T	1.4128	$93.33		$18.67
0007	Level II Incision & Drainage	T	12.5953	$832.03		$166.41
0008	Level III Incision and Drainage	T	19.3873	$1,280.71		$256.15
0012	Level I Debridement & Destruction	T	0.4183	$27.63		$5.53
0013	Level II Debridement & Destruction	T	0.8281	$54.70		$10.94
0015	Level III Debridement & Destruction	T	1.5170	$100.21		$20.05
0016	Level IV Debridement & Destruction	T	2.7288	$180.26		$36.06
0017	Level VI Debridement & Destruction	T	20.2578	$1,338.21		$267.65
0019	Level I Excision/ Biopsy	T	4.4761	$295.69	$71.87	$59.14
0020	Level II Excision/ Biopsy	T	8.2566	$545.42		$109.09
0021	Level III Excision/ Biopsy	T	15.8974	$1,050.17	$219.48	$210.04
0022	Level IV Excision/ Biopsy	T	21.8429	$1,442.92	$354.45	$288.59
0028	Level I Breast Surgery	T	21.4851	$1,419.28	$303.74	$283.86
0029	Level II Breast Surgery	T	33.5744	$2,217.89	$581.52	$443.58
0030	Level III Breast Surgery	T	40.5281	$2,677.25	$747.07	$535.45
0031	Smoking Cessation Services	X	0.1729	$11.42		$2.29
0034	Mental Health Services Composite	S	3.1000	$204.78		$40.96
0035	Vascular Puncture and Minor Diagnostic Procedures	X	0.2186	$14.44		$2.89
0037	Level IV Needle Biopsy/Aspiration Except Bone Marrow	T	13.5176	$892.96	$228.76	$178.60
0039	Level I Implantation of Neurostimulator	S	189.9087	$12,545.18	.	$2,509.04
0040	Percutaneous Implantation of Neurostimulator Electrodes	S	63.6772	$4,206.45	.	$841.29
0041	Level I Arthroscopy	T	29.4149	$1,943.12	.	$388.63
0042	Level II Arthroscopy	T	49.2153	$3,251.11	$804.74	$650.23
0045	Bone/Joint Manipulation Under Anesthesia	T	15.5673	$1,028.36	$268.47	$205.68
0047	Arthroplasty without Prosthesis	T	37.8310	$2,499.08	$537.03	$499.82
0048	Level I Arthroplasty or Implantation with Prosthesis	T	53.1633	$3,511.91	.	$702.39
0049	Level I Musculoskeletal Procedures Except	T	21.7810	$1,438.83	.	$287.77

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
	Hand and Foot					
0050	Level II Musculoskeletal Procedures Except Hand and Foot	T	29.8816	$1,973.95	.	$394.79
0051	Level III Musculoskeletal Procedures Except Hand and Foot	T	45.3534	$2,996.00	.	$599.20
0052	Level IV Musculoskeletal Procedures Except Hand and Foot	T	86.5958	$5,720.43	.	$1,144.09
0053	Level I Hand Musculoskeletal Procedures	T	16.6121	$1,097.38	$253.49	$219.48
0054	Level II Hand Musculoskeletal Procedures	T	27.9994	$1,849.61	.	$369.93
0055	Level I Foot Musculoskeletal Procedures	T	21.6207	$1,428.24	$355.34	$285.65
0056	Level II Foot Musculoskeletal Procedures	T	47.2916	$3,124.04	.	$624.81
0057	Bunion Procedures	T	31.0633	$2,052.01	$475.91	$410.41
0058	Level I Strapping and Cast Application	S	1.0845	$71.64	.	$14.33
0060	Manipulation Therapy	S	0.4302	$28.42	.	$5.69
0061	Laminectomy, Laparoscopy, or Incision for Implantation of Neurostimulator Electr	S	82.9048	$5,476.61	.	$1,095.33
0062	Level I Treatment Fracture/Dislocation	T	25.4442	$1,680.82	$372.87	$336.17
0063	Level II Treatment Fracture/Dislocation	T	42.8656	$2,831.66	.	$566.34
0064	Level III Treatment Fracture/Dislocation	T	62.5691	$4,133.25	$835.79	$826.65
0065	Level I Stereotactic Radiosurgery, MRgFUS, and MEG	S	14.4171	$952.38	.	$190.48
0066	Level II Stereotactic Radiosurgery, MRgFUS, and MEG	S	39.0533	$2,579.82	.	$515.97
0067	Level III Stereotactic Radiosurgery, MRgFUS, and MEG	S	57.5732	$3,803.23	.	$760.65
0069	Thoracoscopy	T	33.5041	$2,213.25	$591.64	$442.65
0070	Thoracentesis/Lavage Procedures	T	5.3343	$352.38	.	$70.48
0071	Level I Endoscopy Upper Airway	T	0.8215	$54.27	$11.20	$10.86
0072	Level II Endoscopy Upper Airway	T	1.8079	$119.43	.	$23.89
0073	Level III Endoscopy Upper Airway	T	4.3850	$289.67	$69.15	$57.94
0074	Level IV Endoscopy Upper Airway	T	18.4160	$1,216.54	$292.25	$243.31
0075	Level V Endoscopy Upper Airway	T	23.4045	$1,546.08	$445.92	$309.22
0076	Level I Endoscopy Lower Airway	T	10.1993	$673.76	$189.82	$134.76
0077	Level I Pulmonary Treatment	S	0.4024	$26.58	$7.74	$5.32
0078	Level II Pulmonary Treatment	S	1.3903	$91.84	.	$18.37
0079	Ventilation Initiation and Management	S	2.9177	$192.74	.	$38.55
0080	Diagnostic Cardiac Catheterization	T	39.2661	$2,593.88	$838.92	$518.78
0082	Coronary or Non-Coronary Atherectomy	T	90.2562	$5,962.23	.	$1,192.45
0083	Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty	T	48.3584	$3,194.51	.	$638.91
0084	Level I Electrophysiologic Procedures	S	10.2559	$677.49	.	$135.50
0085	Level II Electrophysiologic Procedures	T	49.3497	$3,259.99	.	$652.00

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0086	Level III Electrophysiologic Procedures	T	100.1431	$6,615.35	.	$1,323.07
0088	Thrombectomy	T	40.3117	$2,662.95	$655.22	$532.59
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	T	117.7443	$7,778.07	$1,682.28	$1,555.62
0090	Insertion/Replacement of Pacemaker Pulse Generator	T	96.2978	$6,361.34	$1,597.43	$1,272.27
0091	Level II Vascular Ligation	T	43.7923	$2,892.88	.	$578.58
0092	Level I Vascular Ligation	T	27.3614	$1,807.47	.	$361.50
0093	Vascular Reconstruction/Fistula Repair without Device	T	29.0343	$1,917.98	.	$383.60
0094	Level I Resuscitation and Cardioversion	S	2.4181	$159.74	$46.29	$31.95
0095	Cardiac Rehabilitation	S	0.5712	$37.73	$13.86	$7.55
0096	Non-Invasive Vascular Studies	S	1.4327	$94.64	$37.42	$18.93
0097	Cardiac and Ambulatory Blood Pressure Monitoring	X	0.9946	$65.70	$23.79	$13.14
0099	Electrocardiograms	S	0.3949	$26.09	.	$5.22
0100	Cardiac Stress Tests	X	2.5884	$170.99	$41.44	$34.20
0101	Tilt Table Evaluation	S	4.2301	$279.44	$100.24	$55.89
0103	Miscellaneous Vascular Procedures	T	15.7264	$1,038.87	.	$207.78
0104	Transcatheter Placement of Intracoronary Stents	T	85.3503	$5,638.16	.	$1,127.64
0105	Repair/Revision/Removal of Pacemakers, AICDs, or Vascular Devices	T	22.1272	$1,461.70	.	$292.34
0106	Insertion/Replacement of Pacemaker Leads and/or Electrodes	T	50.4825	$3,334.82	.	$666.97
0107	Insertion of Cardioverter-Defibrillator	T	320.0151	$21,139.88	.	$4,227.98
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	T	427.6576	$28,250.63	.	$5,650.13
0110	Transfusion	S	3.3544	$221.59	.	$44.32
0111	Blood Product Exchange	S	11.5004	$759.70	$198.40	$151.94
0112	Apheresis and Stem Cell Procedures	S	30.7865	$2,033.73	$433.29	$406.75
0113	Excision Lymphatic System	T	23.6897	$1,564.92	.	$312.99
0114	Thyroid/Lymphadenectomy Procedures	T	47.2067	$3,118.43	.	$623.69
0115	Cannula/Access Device Procedures	T	32.9660	$2,177.70	.	$435.54
0121	Level I Tube or Catheter Changes or Repositioning	T	4.5958	$303.59	.	$60.72
0126	Level I Urinary and Anal Procedures	T	1.0435	$68.93	$16.21	$13.79
0127	Level IV Stereotactic Radiosurgery, MRgFUS, and MEG	S	115.6797	$7,641.69	.	$1,528.34
0128	Echocardiogram with Contrast	S	8.5705	$566.16	$216.29	$113.24
0129	Level I Closed Treatment Fracture Finger/Toe/Trunk	T	1.5977	$105.54	.	$21.11
0130	Level I Laparoscopy	T	37.8887	$2,502.89	$659.53	$500.58

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0131	Level II Laparoscopy	T	46.3238	$3,060.10	$1,001.89	$612.02
0132	Level III Laparoscopy	T	69.9234	$4,619.07	$1,239.22	$923.82
0133	Level I Skin Repair	T	1.3124	$86.70	$25.67	$17.34
0134	Level II Skin Repair	T	3.4414	$227.34	.	$45.47
0135	Level III Skin Repair	T	4.4306	$292.68	.	$58.54
0136	Level IV Skin Repair	T	15.9750	$1,055.29	.	$211.06
0137	Level V Skin Repair	T	21.0656	$1,391.57	.	$278.32
0138	Level II Closed Treatment Fracture Finger/Toe/Trunk	T	6.1479	$406.12	.	$81.23
0139	Level III Closed Treatment Fracture Finger/Toe/Trunk	T	19.8724	$1,312.75	.	$262.55
0140	Esophageal Dilation without Endoscopy	T	6.5579	$433.21	$91.40	$86.65
0141	Level I Upper GI Procedures	T	8.6526	$571.58	$143.38	$114.32
0142	Small Intestine Endoscopy	T	9.5724	$632.34	$152.78	$126.47
0143	Lower GI Endoscopy	T	8.9884	$593.76	$186.06	$118.76
0146	Level I Sigmoidoscopy and Anoscopy	T	5.6133	$370.81	.	$74.17
0147	Level II Sigmoidoscopy and Anoscopy	T	9.1325	$603.28	.	$120.66
0148	Level I Anal/Rectal Procedures	T	5.8523	$386.60	.	$77.32
0149	Level III Anal/Rectal Procedures	T	23.1877	$1,531.76	.	$306.36
0150	Level IV Anal/Rectal Procedures	T	31.0398	$2,050.46	$437.12	$410.10
0151	Endoscopic Retrograde Cholangio-Pancreatography (ERCP)	T	21.9315	$1,448.77	.	$289.76
0152	Level I Percutaneous Abdominal and Biliary Procedures	T	30.4122	$2,009.00	.	$401.80
0153	Peritoneal and Abdominal Procedures	T	23.4113	$1,546.53	$376.05	$309.31
0154	Hernia/Hydrocele Procedures	T	31.6628	$2,091.61	$464.85	$418.33
0155	Level II Anal/Rectal Procedures	T	12.2139	$806.84	.	$161.37
0156	Level III Urinary and Anal Procedures	T	2.8838	$190.50	.	$38.10
0157	Colorectal Cancer Screening: Barium Enema	S	2.2661	$149.70	.	$29.94
0158	Colorectal Cancer Screening: Colonoscopy	T	7.9944	$528.10	.	$132.03
0159	Colorectal Cancer Screening: Flexible Sigmoidoscopy	S	5.0788	$335.50	.	$83.88
0160	Level I Cystourethroscopy and other Genitourinary Procedures	T	7.2104	$476.31	.	$95.27
0161	Level II Cystourethroscopy and other Genitourinary Procedures	T	18.7931	$1,241.45	.	$248.29
0162	Level III Cystourethroscopy and other Genitourinary Procedures	T	25.5871	$1,690.26	.	$338.06
0163	Level IV Cystourethroscopy and other Genitourinary Procedures	T	35.8662	$2,369.29	.	$473.86
0164	Level II Urinary and Anal Procedures	T	1.8697	$123.51	.	$24.71

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0165	Level IV Urinary and Anal Procedures	T	20.0346	$1,323.47	.	$264.70
0166	Level I Urethral Procedures	T	19.8629	$1,312.12	.	$262.43
0168	Level II Urethral Procedures	T	30.6101	$2,022.07	.	$404.42
0169	Lithotripsy	T	41.8999	$2,767.87	$997.74	$553.58
0170	Dialysis	S	6.5599	$433.34	.	$86.67
0172	Level I Partial Hospitalization (3 services)	P	2.4380	$161.05	.	$32.21
0173	Level II Partial Hospitalization (4 or more services)	P	3.1000	$204.78	.	$40.96
0174	Level IV Laparoscopy	T	119.7237	$7,908.83	$2,208.75	$1,581.77
0181	Level II Male Genital Procedures	T	35.5639	$2,349.32	$621.82	$469.87
0183	Level I Male Genital Procedures	T	22.8376	$1,508.63	.	$301.73
0184	Prostate Biopsy	T	11.5477	$762.83	.	$152.57
0188	Level II Female Reproductive Proc	T	1.4229	$94.00	.	$18.80
0189	Level III Female Reproductive Proc	T	3.0012	$198.26	.	$39.66
0190	Level I Hysteroscopy	T	22.0226	$1,454.79	$424.28	$290.96
0191	Level I Female Reproductive Proc	T	0.1524	$10.07	$2.36	$2.02
0192	Level IV Female Reproductive Proc	T	6.1378	$405.46	.	$81.10
0193	Level V Female Reproductive Proc	T	19.7838	$1,306.90	.	$261.38
0195	Level VI Female Reproductive Procedures	T	33.6934	$2,225.75	$483.80	$445.15
0202	Level VII Female Reproductive Procedures	T	43.7195	$2,888.07	$981.50	$577.62
0203	Level IV Nerve Injections	T	14.3718	$949.39	$240.33	$189.88
0204	Level I Nerve Injections	T	2.4871	$164.30	$40.13	$32.86
0206	Level II Nerve Injections	T	3.6499	$241.11	$51.76	$48.23
0207	Level III Nerve Injections	T	7.1721	$473.78	.	$94.76
0208	Laminotomies and Laminectomies	T	48.6069	$3,210.92	.	$642.19
0209	Level II Extended EEG, Sleep, and Cardiovascular Studies	S	11.4202	$754.41	$268.73	$150.89
0213	Level I Extended EEG, Sleep, and Cardiovascular Studies	S	2.3168	$153.05	$53.58	$30.61
0215	Level I Nerve and Muscle Tests	S	0.5994	$39.60	.	$7.92
0216	Level III Nerve and Muscle Tests	S	2.6652	$176.06	.	$35.22
0218	Level II Nerve and Muscle Tests	S	1.1853	$78.30	.	$15.66
0220	Level I Nerve Procedures	T	18.5109	$1,222.81	.	$244.57
0221	Level II Nerve Procedures	T	35.9602	$2,375.49	.	$475.10
0222	Level II Implantation of Neurostimulator	S	235.6477	$15,566.65	.	$3,113.33
0224	Implantation of Catheter/Reservoir/Shunt	T	42.0410	$2,777.19	.	$555.44
0225	Implantation of Neurostimulator Electrodes, Cranial Nerve	S	109.5182	$7,234.66	.	$1,446.94
0227	Implantation of Drug Infusion Device	T	185.9307	$12,282.40	.	$2,456.48
0229	Transcatherter Placement of Intravascular Shunts	T	92.2507	$6,093.99	.	$1,218.80
0230	Level I Eye Tests & Treatments	S	0.6461	$42.68	.	$8.54

ADDENDUM A.–FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0231	Level III Eye Tests & Treatments	S	2.1549	$142.35	.	$28.47
0232	Level I Anterior Segment Eye Procedures	T	4.6708	$308.55	$77.30	$61.71
0233	Level II Anterior Segment Eye Procedures	T	16.7409	$1,105.89	$266.33	$221.18
0234	Level III Anterior Segment Eye Procedures	T	23.8963	$1,578.57	$511.31	$315.72
0235	Level I Posterior Segment Eye Procedures	T	5.8277	$384.97	.	$77.00
0237	Level II Posterior Segment Eye Procedures	T	22.3269	$1,474.89	.	$294.98
0238	Level I Repair and Plastic Eye Procedures	T	3.1524	$208.24	.	$41.65
0239	Level II Repair and Plastic Eye Procedures	T	7.6973	$508.48	.	$101.70
0240	Level III Repair and Plastic Eye Procedures	T	19.3139	$1,275.86	$309.52	$255.18
0241	Level IV Repair and Plastic Eye Procedures	T	26.0302	$1,719.53	$383.45	$343.91
0242	Level V Repair and Plastic Eye Procedures	T	38.5166	$2,544.37	$597.36	$508.88
0243	Strabismus/Muscle Procedures	T	24.6556	$1,628.72	$430.35	$325.75
0244	Corneal and Amniotic Membrane Transplant	T	37.9664	$2,508.02	$803.26	$501.61
0245	Level I Cataract Procedures without IOL Insert	T	14.1882	$937.26	$214.11	$187.46
0246	Cataract Procedures with IOL Insert	T	24.2955	$1,604.94	$495.96	$320.99
0247	Laser Eye Procedures	T	5.2647	$347.78	$104.31	$69.56
0249	Level II Cataract Procedures without IOL Insert	T	31.3304	$2,069.65	$524.67	$413.93
0250	Level I ENT Procedures	T	1.1110	$73.39	$25.10	$14.68
0251	Level II ENT Procedures	T	3.3069	$218.45	.	$43.69
0252	Level III ENT Procedures	T	7.5330	$497.62	$109.16	$99.53
0253	Level IV ENT Procedures	T	17.2402	$1,138.87	$282.29	$227.78
0254	Level V ENT Procedures	T	24.7557	$1,635.34	.	$327.07
0256	Level VI ENT Procedures	T	41.8741	$2,766.16	.	$553.24
0259	Level VII ENT Procedures	T	401.1259	$26,497.98	$8,543.66	$5,299.60
0260	Level I Plain Film Except Teeth	X	0.6767	$44.70	.	$8.94
0261	Level II Plain Film Except Teeth Including Bone Density Measurement	X	1.1269	$74.44	.	$14.89
0262	Plain Film of Teeth	X	0.4855	$32.07	.	$6.42
0263	Level I Miscellaneous Radiology Procedures	X	3.0202	$199.51	.	$39.91
0265	Level I Diagnostic and Screening Ultrasound	S	0.9461	$62.50	$22.35	$12.50
0266	Level II Diagnostic and Screening Ultrasound	S	1.4801	$97.77	$37.80	$19.56
0267	Level III Diagnostic and Screening Ultrasound	S	2.3186	$153.16	$60.50	$30.64

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0269	Level II Echocardiogram Without Contrast Except Transesophageal	S	6.5300	$431.37	.	$86.28
0270	Transesophageal Echocardiogram Without Contrast	S	8.3489	$551.52	$141.32	$110.31
0272	Fluoroscopy	X	1.2597	$83.21	$31.15	$16.65
0274	Myelography	S	7.1945	$475.26	.	$95.06
0275	Arthrography	S	4.0175	$265.39	$69.09	$53.08
0276	Level I Digestive Radiology	S	1.3298	$87.85	$34.87	$17.57
0277	Level II Digestive Radiology	S	2.1621	$142.83	$54.52	$28.57
0278	Diagnostic Urography	S	2.6340	$174.00	$59.40	$34.80
0279	Level II Angiography and Venography	S	29.5853	$1,954.38	.	$390.88
0280	Level III Angiography and Venography	S	44.7368	$2,955.27	.	$591.06
0282	Miscellaneous Computed Axial Tomography	S	1.5897	$105.01	$37.81	$21.01
0283	Computed Tomography with Contrast	S	4.6595	$307.80	$100.37	$61.56
0284	Magnetic Resonance Imaging and Magnetic Resonance Angiography with Contrast	S	6.4701	$427.41	$148.40	$85.49
0288	Bone Density:Axial Skeleton	S	1.0887	$71.92	$28.66	$14.39
0293	Level V Anterior Segment Eye Procedures	T	104.7499	$6,919.67	.	$1,383.94
0299	Hyperthermia and Radiation Treatment Procedures	S	5.6497	$373.21	.	$74.65
0300	Level I Radiation Therapy	S	1.4211	$93.88	.	$18.78
0301	Level II Radiation Therapy	S	2.3018	$152.05	.	$30.41
0303	Treatment Device Construction	X	2.8484	$188.16	$66.95	$37.64
0304	Level I Therapeutic Radiation Treatment Preparation	X	1.7364	$114.70	$38.68	$22.94
0305	Level II Therapeutic Radiation Treatment Preparation	X	3.8706	$255.69	$91.38	$51.14
0307	Myocardial Positron Emission Tomography (PET) imaging	S	17.5127	$1,156.87	$241.53	$231.38
0308	Non-Myocardial Positron Emission Tomography (PET) imaging	S	15.6969	$1,036.92	.	$207.39
0310	Level III Therapeutic Radiation Treatment Preparation	X	13.5167	$892.90	$325.27	$178.58
0312	Radioelement Applications	S	6.5193	$430.66	.	$86.14
0313	Brachytherapy	S	11.1000	$733.25	$293.30	$146.65
0315	Level III Implantation of Neurostimulator	S	277.2288	$18,313.46	.	$3,662.70
0317	Level II Miscellaneous Radiology Procedures	X	5.1044	$337.19	.	$67.44
0320	Electroconvulsive Therapy	S	5.7528	$380.02	$80.06	$76.01
0322	Brief Individual Psychotherapy	S	1.3097	$86.52	.	$17.31
0323	Extended Individual Psychotherapy	S	1.6317	$107.79	.	$21.56

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0324	Family Psychotherapy	S	2.4859	$164.22	.	$32.85
0325	Group Psychotherapy	S	0.9800	$64.74	$13.81	$12.95
0330	Dental Procedures	S	7.6534	$505.58	.	$101.12
0332	Computed Tomography without Contrast	S	2.9426	$194.39	$75.24	$38.88
0333	Computed Tomography without Contrast followed by Contrast)	S	5.1615	$340.96	$119.01	$68.20
0336	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast	S	5.2689	$348.06	$137.40	$69.62
0337	Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast f	S	8.1548	$538.70	$199.53	$107.74
0340	Minor Ancillary Procedures	X	0.6462	$42.69	.	$8.54
0341	Skin Tests	X	0.0834	$5.51	$2.14	$1.11
0342	Level I Pathology	X	0.1523	$10.06	$2.02	$2.02
0343	Level III Pathology	X	0.5230	$34.55	$10.84	$6.91
0344	Level IV Pathology	X	0.8223	$54.32	$15.66	$10.87
0345	Level I Transfusion Laboratory Procedures	X	0.2194	$14.49	.	$2.90
0346	Level II Transfusion Laboratory Procedures	X	0.3807	$25.15	.	$5.03
0347	Level III Transfusion Laboratory Procedures	X	0.7337	$48.47	$9.94	$9.70
0350	Administration of flu and PPV vaccine	S	0.3768	$24.89	.	$0.00
0360	Level I Alimentary Tests	X	1.5113	$99.83	$33.88	$19.97
0361	Level II Alimentary Tests	X	3.9733	$262.47	$83.23	$52.50
0363	Level I Otorhinolaryngologic Function Tests	X	0.9042	$59.73	$17.10	$11.95
0364	Level I Audiometry	X	0.4730	$31.25	$7.06	$6.25
0365	Level II Audiometry	X	1.2779	$84.42	$18.52	$16.89
0366	Level III Audiometry	X	1.7097	$112.94	$25.79	$22.59
0367	Level I Pulmonary Test	X	0.5627	$37.17	$13.76	$7.44
0368	Level II Pulmonary Tests	X	0.8326	$55.00	$20.93	$11.00
0369	Level III Pulmonary Tests	X	2.7955	$184.67	$44.18	$36.94
0370	Allergy Tests	X	1.4677	$96.95	.	$19.39
0373	Level I Neuropsychological Testing	X	1.3408	$88.57	.	$17.72
0375	Ancillary Outpatient Services When Patient Expires	S	85.8765	$5,672.92	.	$1,134.59
0377	Level II Cardiac Imaging	S	11.7188	$774.13	$158.84	$154.83
0378	Level II Pulmonary Imaging	S	4.9163	$324.77	$125.33	$64.96
0379	Injection adenosine 6 MG	K	.	$9.25	.	$1.85
0381	Single Allergy Tests	X	0.3517	$23.23	.	$4.65
0382	Level II Neuropsychological Testing	X	2.4430	$161.38	.	$32.28
0383	Cardiac Computed Tomographic Imaging	S	4.2793	$282.69	$110.53	$56.54

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0384	GI Procedures with Stents	T	25.7008	$1,697.77	.	$339.56
0385	Level I Prosthetic Urological Procedures	S	97.5997	$6,447.34	.	$1,289.47
0386	Level II Prosthetic Urological Procedures	S	152.9428	$10,103.25	.	$2,020.65
0387	Level II Hysteroscopy	T	36.6478	$2,420.92	$655.55	$484.19
0388	Discography	S	22.7705	$1,504.20	.	$300.84
0389	Level I Non-imaging Nuclear Medicine	S	1.7779	$117.45	$33.81	$23.49
0390	Level I Endocrine Imaging	S	2.0640	$136.35	$52.15	$27.27
0391	Level II Endocrine Imaging	S	3.3593	$221.91	$66.18	$44.39
0392	Level II Non-imaging Nuclear Medicine	S	2.4943	$164.77	$43.95	$32.96
0393	Hematologic Processing & Studies	S	6.0581	$400.19	$82.04	$80.04
0394	Hepatobiliary Imaging	S	4.1626	$274.98	$99.32	$55.00
0395	GI Tract Imaging	S	3.6804	$243.12	$89.73	$48.63
0396	Bone Imaging	S	3.7205	$245.77	$95.02	$49.16
0397	Vascular Imaging	S	2.8298	$186.93	$46.29	$37.39
0398	Level I Cardiac Imaging	S	4.7291	$312.40	$100.06	$62.48
0400	Hematopoietic Imaging	S	3.9752	$262.60	$93.22	$52.52
0401	Level I Pulmonary Imaging	S	3.2040	$211.65	$76.52	$42.33
0402	Level II Nervous System Imaging	S	8.3063	$548.71	$111.42	$109.75
0403	Level I Nervous System Imaging	S	2.8236	$186.52	$72.42	$37.31
0404	Renal and Genitourinary Studies	S	4.9803	$328.99	$84.11	$65.80
0406	Level I Tumor/Infection Imaging	S	4.5288	$299.17	$90.99	$59.84
0407	Level I Radionuclide Therapy	S	3.2584	$215.25	$78.13	$43.05
0408	Level III Tumor/Infection Imaging	S	15.1962	$1,003.85	.	$200.77
0409	Red Blood Cell Tests	X	0.1168	$7.72	$2.20	$1.55
0412	IMRT Treatment Delivery	S	6.2192	$410.83	.	$82.17
0413	Level II Radionuclide Therapy	S	5.4802	$362.02	.	$72.41
0414	Level II Tumor/Infection Imaging	S	8.5379	$564.01	$214.44	$112.81
0415	Level II Endoscopy Lower Airway	T	25.1663	$1,662.46	$459.92	$332.50
0418	Insertion of Left Ventricular Pacing Elect.	T	138.4242	$9,144.16	.	$1,828.84
0422	Level II Upper GI Procedures	T	25.3785	$1,676.48	$448.81	$335.30
0423	Level II Percutaneous Abdominal and Biliary Procedures	T	46.5013	$3,071.83	.	$614.37
0425	Level II Arthroplasty or Implantation with Prosthesis	T	121.7668	$8,043.79	.	$1,608.76
0426	Level II Strapping and Cast Application	S	2.4305	$160.56	.	$32.12
0427	Level II Tube or Catheter Changes or Repositioning	T	15.5994	$1,030.48	.	$206.10
0428	Level III Sigmoidoscopy and Anoscopy	T	23.6827	$1,564.46	.	$312.90
0429	Level V Cystourethroscopy and other Genitourinary Procedures	T	45.8088	$3,026.08	.	$605.22
0432	Health and Behavior Services	S	0.4065	$26.85	.	$5.37
0433	Level II Pathology	X	0.2498	$16.50	$5.17	$3.30

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0434	Cardiac Defect Repair	T	153.6340	$10,148.91	.	$2,029.79
0436	Level I Drug Administration	S	0.3768	$24.89	.	$4.98
0437	Level II Drug Administration	S	0.5469	$36.13	.	$7.23
0438	Level III Drug Administration	S	1.1152	$73.67	.	$14.74
0439	Level IV Drug Administration	S	1.9470	$128.62	.	$25.73
0440	Level V Drug Administration	S	2.8454	$187.96	.	$37.60
0442	Dosimetric Drug Administration	S	28.9015	$1,909.20	.	$381.84
0604	Level 1 Hospital Clinic Visits	V	0.8277	$54.68	.	$10.94
0605	Level 2 Hospital Clinic Visits	V	1.0439	$68.96	.	$13.80
0606	Level 3 Hospital Clinic Visits	V	1.3585	$89.74	.	$17.95
0607	Level 4 Hospital Clinic Visits	V	1.7192	$113.57	.	$22.72
0608	Level 5 Hospital Clinic Visits	V	2.4477	$161.69	.	$32.34
0609	Level 1 Type A Emergency Visits	V	0.7972	$52.66	$12.70	$10.54
0613	Level 2 Type A Emergency Visits	V	1.3040	$86.14	$21.06	$17.23
0614	Level 3 Type A Emergency Visits	V	2.0694	$136.70	$34.50	$27.34
0615	Level 4 Type A Emergency Visits	V	3.2987	$217.91	$48.49	$43.59
0616	Level 5 Emergency Visits	V	4.9032	$323.90	$72.86	$64.78
0617	Critical Care	S	7.3479	$485.39	$111.59	$97.08
0618	Trauma Response with Critical Care	S	14.1558	$935.12	.	$187.03
0621	Level I Vascular Access Procedures	T	11.0653	$730.96	.	$146.20
0622	Level II Vascular Access Procedures	T	24.9153	$1,645.88	.	$329.18
0623	Level III Vascular Access Procedures	T	29.7476	$1,965.10	.	$393.02
0624	Phlebotomy and Minor Vascular Access Device Procedures	X	0.6043	$39.92	$12.65	$7.99
0626	Level 1 Type B Emergency Visits	V	0.6840	$45.18	.	$9.04
0627	Level 2 Type B Emergency Visits	V	0.9302	$61.45	.	$12.29
0628	Level 3 Type B Emergency Visits	V	1.3418	$88.64	.	$17.73
0629	Level 4 Type B Emergency Visits	V	2.4093	$159.16	.	$31.84
0648	Level IV Breast Surgery	T	60.1165	$3,971.24	.	$794.25
0651	Complex Interstitial Radiation Source Application	S	13.1120	$866.17	.	$173.24
0652	Insertion of Intraperitoneal and Pleural Catheters	T	29.8670	$1,972.98	.	$394.60
0653	Vascular Reconstruction/Fistula Repair with Device	T	46.8513	$3,094.95	.	$618.99
0654	Insertion/Replacement of a permanent dual chamber pacemaker	T	108.9884	$7,199.66	.	$1,439.94
0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	T	143.9957	$9,512.21	.	$1,902.45
0656	Transcatheter Placement of Intracoronary Drug-Eluting Stents	T	116.0944	$7,669.08	.	$1,533.82
0659	Hyperbaric Oxygen	S	1.5677	$103.56	.	$20.72

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0660	Level II Otorhinolaryngologic Function Tests	X	1.5831	$104.58	$28.06	$20.92
0661	Level V Pathology	X	2.4143	$159.49	$57.69	$31.90
0662	CT Angiography	S	5.3264	$351.86	$118.88	$70.38
0664	Level I Proton Beam Radiation Therapy	S	10.6477	$703.38	.	$140.68
0665	Bone Density:AppendicularSkeleton	S	0.4798	$31.70	$12.67	$6.34
0667	Level II Proton Beam Radiation Therapy	S	12.7244	$840.56	.	$168.12
0668	Level I Angiography and Venography	S	10.3351	$682.73	.	$136.55
0672	Level III Posterior Segment Eye Procedures	T	38.1751	$2,521.81	.	$504.37
0673	Level IV Anterior Segment Eye Procedures	T	40.9535	$2,705.35	$649.56	$541.07
0674	Prostate Cryoablation	T	122.0254	$8,060.88	.	$1,612.18
0676	Thrombolysis and Thrombectomy	T	2.4525	$162.01	.	$32.41
0678	External Counterpulsation	T	1.5475	$102.23	.	$20.45
0679	Level II Resuscitation and Cardioversion	S	5.4782	$361.88	$95.30	$72.38
0680	Insertion of Patient Activated Event Recorders	S	72.8054	$4,809.45	.	$961.89
0681	Knee Arthroplasty	T	186.5341	$12,322.26	.	$2,464.46
0682	Level V Debridement & Destruction	T	7.2265	$477.38	$158.65	$95.48
0683	Level II Photochemotherapy	S	2.7022	$178.50	.	$35.70
0685	Level III Needle Biopsy/Aspiration Except Bone Marrow	T	9.5785	$632.75	.	$126.55
0687	Revision/Removal of Neurostimulator Electrodes	T	19.6378	$1,297.25	$397.37	$259.45
0688	Revision/Removal of Neurostimulator Pulse Generator Receiver	T	29.5464	$1,951.81	$778.69	$390.37
0689	Level II Electronic Analysis of Devices	S	0.5941	$39.25	.	$7.85
0690	Level I Electronic Analysis of Devices	S	0.3508	$23.17	$8.67	$4.64
0691	Level IV Electronic Analysis of Devices	S	2.4647	$162.82	$50.49	$32.57
0692	Level III Electronic Analysis of Devices	S	1.6537	$109.24	.	$21.85
0694	Mohs Surgery	T	4.5047	$297.58	$91.69	$59.52
0697	Level I Echocardiogram Without Contrast Except Transesophageal	S	3.8610	$255.05	.	$51.01
0698	Level II Eye Tests & Treatments	S	0.9338	$61.69	.	$12.34
0699	Level IV Eye Tests & Treatments	T	14.4782	$956.42	.	$191.29
0701	Sr89 strontium	H	.		.	.
0702	Sm 153 lexidronm	H	.		.	.
0726	Dexrazoxane HCl injection	K	.	$263.77	.	$52.76
0728	Filgrastim 300 mcg injection	K	.	$196.54	.	$39.31
0730	Pamidronate disodium	K	.	$28.68	.	$5.74
0731	Sargramostim injection	K	.	$25.76	.	$5.16
0732	Mesna injection	K	.	$6.83	.	$1.37

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0735	Ampho b cholesteryl sulfate	K	.	$11.78	.	$2.36
0736	Amphotericin b liposome inj	K	.	$15.82	.	$3.17
0738	Rasburicase	K	.	$152.34	.	$30.47
0747	Chlorothiazide sodium inj	K	.	$189.58	.	$37.92
0750	Dolasetron mesylate	K	.	$4.52	.	$0.91
0751	Mechlorethamine hcl inj	K	.	$141.96	.	$28.40
0752	Dactinomycin injection	K	.	$486.26	.	$97.26
0759	Naltrexone, depot form	K	.	$1.85	.	$0.37
0760	Anidulafungin injection	K	.	$1.34	.	$0.27
0763	Dolasetron mesylate oral	K	.	$56.00	.	$11.20
0764	Granisetron hcl injection	K	.	$4.25	.	$0.85
0765	Granisetron hcl 1 mg oral	K	.	$17.54	.	$3.51
0768	Ondansetron hcl injection	K	.	$0.19	.	$0.04
0769	Ondansetron hcl 8 mg oral	K	.	$3.86	.	$0.78
0800	Leuprolide acetate	K	.	$435.72	.	$87.15
0802	Etoposide oral	K	.	$28.79	.	$5.76
0804	Vivaglobin, inj	K	.	$6.94	.	$1.39
0807	Aldesleukin injection	K	.	$792.77	.	$158.56
0809	Bcg live intravesical vac	K	.	$112.33	.	$22.47
0810	Goserelin acetate implant	K	.	$185.87	.	$37.18
0812	Carmustine injection	K	.	$161.32	.	$32.27
0814	Asparaginase injection	K	.	$56.97	.	$11.40
0820	Daunorubicin injection	K	.	$16.58	.	$3.32
0821	Daunorubicin citrate inj	K	.	$55.04	.	$11.01
0823	Docetaxel injection	K	.	$328.32	.	$65.67
0825	Nelarabine injection	G	.	$96.09	.	$18.86
0827	Floxuridine injection	K	.	$49.58	.	$9.92
0828	Gemcitabine hcl injection	K	.	$132.54	.	$26.51
0830	Irinotecan injection	K	.	$36.30	.	$7.26
0831	Ifosfomide injection	K	.	$33.16	.	$6.64
0832	Idarubicin hcl injection	K	.	$230.09	.	$46.02
0834	Interferon alfa-2a inj	K	.	$39.76	.	$7.96
0835	Inj cosyntropin	K	.	$95.34	.	$19.07
0836	Interferon alfa-2b inj	K	.	$14.45	.	$2.89
0838	Interferon gamma 1-b inj	K	.	$345.15	.	$69.03
0840	Inj melphalan hydrochl	K	.	$1,593.94	.	$318.79
0842	Fludarabine phosphate inj	K	.	$217.03	.	$43.41
0843	Pegaspargase injection	K	.	$2,569.13	.	$513.83
0844	Pentostatin injection	K	.	$1,592.03	.	$318.41
0849	Rituximab injection	K	.	$524.58	.	$104.92
0850	Streptozocin injection	K	.	$193.00	.	$38.60

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0851	Thiotepa injection	K	.	$92.76	.	$18.56
0852	Topotecan injection	K	.	$913.11	.	$182.63
0855	Vinorelbine tartrate inj	K	.	$16.26	.	$3.26
0856	Porfimer sodium injection	K	.	$2,490.53	.	$498.11
0858	Inj cladribine	K	.	$28.79	.	$5.76
0861	Leuprolide acetate injeciton	K	.	$6.56	.	$1.32
0863	Paclitaxel injection	K	.	$10.83	.	$2.17
0864	Mitoxantrone hydrochl	K	.	$85.55	.	$17.11
0865	Interferon alfa-n3 inj	K	.	$17.89	.	$3.58
0868	Oral aprepitant	K	.	$5.24	.	$1.05
0873	Hyalgan/supartz inj per dose	K	.	$97.02	.	$19.41
0874	Synvisc inj per dose	K	.	$181.29	.	$36.26
0875	Euflexxa inj per dose	K	.	$107.54	.	$21.51
0877	Orthovisc inj per dose	K	.	$176.11	.	$35.23
0878	Gallium nitrate injection	K	.	$1.56	.	$0.32
0883	Fondaparinux sodium	K	.	$6.03	.	$1.21
0884	Rho d immune globulin inj	K	.	$82.95	.	$16.59
0887	Azathioprine parenteral	K	.	$89.27	.	$17.86
0888	Cyclosporine oral	K	.	$3.61	.	$0.73
0890	Lymphocyte immune globulin	K	.	$431.18	.	$86.24
0891	Tacrolimus oral	K	.	$3.82	.	$0.77
0898	Gamma globulin 2 CC inj	K	.	$23.72	.	$4.75
0899	Gamma globulin 3 CC inj	K	.	$35.58	.	$7.12
0900	Alglucerase injection	K	.	$39.63	.	$7.93
0901	Alpha 1 proteinase inhibitor	K	.	$3.62	.	$0.73
0902	Botulinum toxin a per unit	K	.	$5.30	.	$1.06
0903	Cytomegalovirus imm IV /vial	K	.	$862.24	.	$172.45
0904	Gamma globulin 4 CC inj	K	.	$47.44	.	$9.49
0906	RSV-ivig	K	.	$15.87	.	$3.18
0910	Interferon beta-1b / .25 MG	K	.	$107.92	.	$21.59
0913	Ganciclovir long act implant	K	.	$16,640.00	.	$3,328.00
0916	Injection imiglucerase /unit	K	.	$3.96	.	$0.80
0917	Adenosine injection	K	.	$69.44	.	$13.89
0919	Gamma globulin 5 CC inj	K	.	$59.31	.	$11.87
0920	Gamma globulin 6 CC inj	K	.	$71.18	.	$14.24
0921	Gamma globulin 7 CC inj	K	.	$82.99	.	$16.60
0922	Gamma globulin 8 CC inj	K	.	$94.89	.	$18.98
0923	Gamma globulin 9 CC inj	K	.	$106.78	.	$21.36
0924	Gamma globulin 10 CC inj	K	.	$118.61	.	$23.73
0925	Factor viii	K	.	$0.81	.	$0.17
0927	Factor viii recombinant	K	.	$1.06	.	$0.22

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
0928	Factor ix complex	K	.	$0.80	.	$0.16
0929	Anti-inhibitor	K	.	$1.46	.	$0.30
0931	Factor IX non-recombinant	K	.	$0.88	.	$0.18
0932	Factor IX recombinant	K	.	$1.05	.	$0.21
0933	Gamma globulin > 10 CC inj	K	.	$118.61	.	$23.73
0934	Capecitabine, oral	K	.	$16.04	.	$3.21
0935	Clonidine hydrochloride	K	.	$63.41	.	$12.69
0943	Octagam injection	K	.	$35.18	.	$7.04
0944	Gammagard liquid injection	K	.	$34.35	.	$6.87
0945	Rhophylac injection	K	.	$5.15	.	$1.03
0946	Hepagam b im injection	G	.	$43.92	.	$8.62
0947	Flebogamma injection	K	.	$35.02	.	$7.01
0948	Gamunex injection	K	.	$34.14	.	$6.83
0949	Frozen plasma, pooled, sd	R	0.8906	$58.83	.	$11.77
0950	Whole blood for transfusion	R	3.4878	$230.40	.	$46.08
0951	Reclast injection	G	.	$216.61	.	$42.50
0952	Cryoprecipitate each unit	R	0.6428	$42.46	.	$8.50
0954	RBC leukocytes reduced	R	2.8598	$188.92	.	$37.79
0955	Plasma, frz between 8-24hour	R	1.1447	$75.62	.	$15.13
0956	Plasma protein fract,5%,50ml	R	0.2365	$15.62	.	$3.13
0957	Platelets, each unit	R	1.1088	$73.25	.	$14.65
0958	Plaelet rich plasma unit	R	5.9788	$394.95	.	$78.99
0959	Red blood cells unit	R	2.0712	$136.82	.	$27.37
0960	Washed red blood cells unit	R	3.9607	$261.64	.	$52.33
0961	Albumin (human),5%, 50ml	K		$19.12	.	$3.83
0963	Albumin (human), 5%, 250 ml	K		$70.02	.	$14.01
0964	Albumin (human), 25%, 20 ml	K		$24.67	.	$4.94
0965	Albumin (human), 25%, 50ml	K		$69.22	.	$13.85
0966	Plasmaprotein fract,5%,250ml	R	2.9712	$196.27	.	$39.26
0967	Blood split unit	R	0.4711	$31.12	.	$6.23
0968	Platelets leukoreduced irrad	R	1.9405	$128.19	.	$25.64
0969	RBC leukoreduced irradiated	R	3.8046	$251.33	.	$50.27
0999	Edetate calcium disodium inj	K	.	$49.29	.	$9.86
1009	Cryoprecipitatereducedplasma	R	1.2892	$85.16	.	$17.04
1010	Blood, l/r, cmv-neg	R	2.1819	$144.13	.	$28.83
1011	Platelets, hla-m, l/r, unit	R	10.7766	$711.89	.	$142.38
1013	Platelets leukocytes reduced	R	1.6904	$111.67	.	$22.34
1015	Injection glatiramer acetate	K	.	$63.46	.	$12.70
1016	Blood, l/r, froz/degly/wash	R	1.5392	$101.68	.	$20.34
1017	Plt, aph/pher, l/r, cmv-neg	R	7.2725	$480.41	.	$96.09
1018	Blood, l/r, irradiated	R	3.4259	$226.31	.	$45.27

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
1019	Plate pheres leukoredu irrad	R	9.8927	$653.50	.	$130.70
1020	Plt, pher, l/r cmv-neg, irr	R	9.8282	$649.24	.	$129.85
1021	RBC, frz/deg/wsh, l/r, irrad	R	6.4286	$424.67	.	$84.94
1022	RBC, l/r, cmv-neg, irrad	R	4.5631	$301.43	.	$60.29
1023	Pralidoxime chloride inj	K	.	$83.55	.	$16.71
1052	Injection, voriconazole	K	.	$5.19	.	$1.04
1064	I131 iodide cap, rx	H	.		.	.
1083	Adalimumab injection	K	.	$338.53	.	$67.71
1084	Denileukin diftitox inj	K	.	$1,405.27	.	$281.06
1086	Temozolomide	K	.	$8.09	.	$1.62
1138	Hepagam b intravenous, inj	G	.	$43.92	.	$8.62
1139	Protein c concentrate	K	.	$11.96	.	$2.40
1142	Supprelin LA implant	G	.	$14,609.22	.	$2,866.71
1150	I131 iodide sol, rx	H	.		.	.
1166	Cytarabine liposome inj	K	.	$439.71	.	$87.95
1167	Inj, epirubicin hcl	K	.	$5.34	.	$1.07
1168	Inj, temsirolimus	G	.	$47.90	.	$9.40
1178	Busulfan injection	K	.	$11.93	.	$2.39
1186	Acetylcysteine injection	K	.	$2.15	.	$0.43
1189	Foscarnet sodium injection	K	.	$10.50	.	$2.10
1203	Verteporfin injection	K	.	$9.15	.	$1.83
1204	Cyclosporin parenteral	K	.	$19.01	.	$3.81
1206	Dimecaprol injection	K	.	$26.26	.	$5.26
1207	Octreotide injection, depot	K	.	$101.89	.	$20.38
1208	Factor VIII (porcine)	K		$0.98	.	$0.20
1209	Diethylstilbestrol injection	K		$78.08	.	$15.62
1211	Oxytetracycline injection	K		$165.50	.	$33.10
1212	Diphtheria antitoxin	K		$182.05	.	$36.41
1213	Antihemophilic viii/vwf comp	K	.	$0.81		$0.17
1214	Inj IVIG privigen 500 mg	G	.	$33.64	.	$6.60
1216	Lyme disease vaccine, im	K		$72.67	.	$14.54
1217	Penicillin g benzathine inj	K		$31.99	.	$6.40
1218	Trifluprom azine hcl inj	K		$20.51	.	$4.11
1219	Dtap-ipv vacc 4-6 yr im	K	.	$49.92	.	$9.98
1220	Calcitonin salmon injection	K	.	$48.04	.	$9.61
1221	Dimethyl sulfoxide 50%	K	.	$64.31	.	$12.87
1222	Pentastarch 10% solution	K	.	$158.76	.	$31.76
1223	Pentobarbital sodium inj	K	.	$7.78	.	$1.56
1224	Sincalide injection	K	.	$60.01	.	$12.01
1225	Somatrem injection	K	.	$43.99	.	$8.80
1226	Inj streptokinase /250000 IU	K	.	$78.00	.	$15.60

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
1227	Urea injection	K	.	$73.95	.	$14.79
1228	Hyaluronidase recombinant	K	.	$0.48	.	$0.10
1230	Nabilone oral	K	.	$16.64	.	$3.33
1231	Plicamycin (mithramycin) inj	K	.	$77.49	.	$15.50
1232	Mitomycin 5 MG inj	K	.	$15.56	.	$3.12
1233	Mitomycin 20 MG inj	K	.	$62.25	.	$12.45
1234	Mitomycin 40 MG inj	K	.	$124.50	.	$24.90
1235	Valrubicin injection	K	.	$384.38	.	$76.88
1236	Levoleucovorin injection	K	.	$1.03	.	$0.21
1237	Inj iron dextran	K	.	$11.59	.	$2.32
1238	Topotecan oral	K	.	$68.58	.	$13.72
1239	Rotavirus vacc 2 dose oral	K	.	$106.60	.	$21.32
1240	Apligraf skin sub	K		$30.92		$6.18
1241	Oasis wound matrix skin sub	K		$4.00		$0.80
1242	Oasis burn matrix skin sub	K		$4.00		$0.80
1243	Integra BMWD skin sub	K		$11.13		$2.23
1244	Integra DRT skin sub	K		$11.13		$2.23
1245	Dermagraft skin sub	K		$37.76		$7.55
1246	Graftjacket skin sub	K		$86.03		$17.21
1247	Integra matrix skin sub	K		$16.83		$3.37
1248	Primatrix skin sub	K		$34.41		$6.88
1249	Cymetra allograft	K		$376.03		$75.21
1250	Graftjacket express allograft	K		$376.03		$75.21
1251	Integra flowable wound matri	G		$875.21		$171.74
1280	Corticotropin injection	K	.	$2,310.04	.	$462.01
1436	Etidronate disodium inj	K	.	$70.06	.	$14.02
1491	New Technology - Level IA ($0-$10)	S	.	$5.00	.	$1.00
1492	New Technology - Level IB ($10-$20)	S	.	$15.00	.	$3.00
1493	New Technology - Level IC ($20-$30)	S	.	$25.00	.	$5.00
1494	New Technology - Level ID ($30-$40)	S	.	$35.00	.	$7.00
1495	New Technology - Level IE ($40-$50)	S	.	$45.00	.	$9.00
1496	New Technology - Level IA ($0-$10)	T	.	$5.00	.	$1.00
1497	New Technology - Level IB($10-$20)	T	.	$15.00	.	$3.00
1498	New Technology - Level IC ($20-$30)	T	.	$25.00	.	$5.00
1499	New Technology - Level ID($30-$40)	T	.	$35.00	.	$7.00
1500	New Technology - Level IE ($40-$50)	T	.	$45.00	.	$9.00
1502	New Technology - Level II ($50 - $100)	S	.	$75.00	.	$15.00
1503	New Technology - Level III ($100 - $200)	S	.	$150.00	.	$30.00
1504	New Technology - Level IV ($200 - $300)	S	.	$250.00	.	$50.00
1505	New Technology - Level V ($300 - $400)	S	.	$350.00	.	$70.00
1506	New Technology - Level VI ($400 - $500)	S	.	$450.00	.	$90.00

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
1507	New Technology - Level VII ($500 - $600)	S	.	$550.00	.	$110.00
1508	New Technology - Level VIII ($600 - $700)	S	.	$650.00	.	$130.00
1509	New Technology - Level IX ($700 - $800)	S	.	$750.00	.	$150.00
1510	New Technology - Level X ($800 - $900)	S	.	$850.00	.	$170.00
1511	New Technology - Level XI ($900 - $1000)	S	.	$950.00	.	$190.00
1512	New Technology - Level XII ($1000 - $1100)	S	.	$1,050.00	.	$210.00
1513	New Technology - Level XIII ($1100 - $1200)	S	.	$1,150.00	.	$230.00
1514	New Technology - Level XIV ($1200- $1300)	S	.	$1,250.00	.	$250.00
1515	New Technology - Level XV ($1300 - $1400)	S	.	$1,350.00	.	$270.00
1516	New Technology - Level XVI ($1400 - $1500)	S	.	$1,450.00	.	$290.00
1517	New Technology - Level XVII ($1500- $1600)	S	.	$1,550.00	.	$310.00
1518	New Technology - Level XVIII ($1600- $1700)	S	.	$1,650.00	.	$330.00
1519	New Technology - Level IXX ($1700- $1800)	S	.	$1,750.00	.	$350.00
1520	New Technology - Level XX ($1800- $1900)	S	.	$1,850.00	.	$370.00
1521	New Technology - Level XXI ($1900- $2000)	S	.	$1,950.00	.	$390.00
1522	New Technology - Level XXII ($2000- $2500)	S	.	$2,250.00	.	$450.00
1523	New Technology - Level XXIII ($2500- $3000)	S	.	$2,750.00	.	$550.00
1524	New Technology - Level XXIV ($3000- $3500)	S	.	$3,250.00	.	$650.00
1525	New Technology - Level XXV ($3500- $4000)	S	.	$3,750.00	.	$750.00
1526	New Technology - Level XXVI ($4000- $4500)	S	.	$4,250.00	.	$850.00
1527	New Technology - Level XXVII ($4500- $5000)	S	.	$4,750.00	.	$950.00
1528	New Technology - Level XXVIII ($5000- $5500)	S	.	$5,250.00	.	$1,050.00
1529	New Technology - Level XXIX ($5500- $6000)	S	.	$5,750.00	.	$1,150.00
1530	New Technology - Level XXX ($6000- $6500)	S	.	$6,250.00	.	$1,250.00
1531	New Technology - Level XXXI ($6500-	S	.	$6,750.00	.	$1,350.00

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
	$7000)					
1532	New Technology - Level XXXII ($7000-$7500)	S	.	$7,250.00	.	$1,450.00
1533	New Technology - Level XXXIII ($7500-$8000)	S	.	$7,750.00	.	$1,550.00
1534	New Technology - Level XXXIV ($8000-$8500)	S	.	$8,250.00	.	$1,650.00
1535	New Technology - Level XXXV ($8500-$9000)	S	.	$8,750.00	.	$1,750.00
1536	New Technology - Level XXXVI ($9000-$9500)	S	.	$9,250.00	.	$1,850.00
1537	New Technology - Level XXXVII ($9500-$10000)	S	.	$9,750.00	.	$1,950.00
1539	New Technology - Level II ($50 - $100)	T	.	$75.00	.	$15.00
1540	New Technology - Level III ($100 - $200)	T	.	$150.00	.	$30.00
1541	New Technology - Level IV ($200 - $300)	T	.	$250.00	.	$50.00
1542	New Technology - Level V ($300 - $400)	T	.	$350.00	.	$70.00
1543	New Technology - Level VI ($400 - $500)	T	.	$450.00	.	$90.00
1544	New Technology - Level VII ($500 - $600)	T	.	$550.00	.	$110.00
1545	New Technology - Level VIII ($600 - $700)	T	.	$650.00	.	$130.00
1546	New Technology - Level IX ($700 - $800)	T	.	$750.00	.	$150.00
1547	New Technology - Level X ($800 - $900)	T	.	$850.00	.	$170.00
1548	New Technology - Level XI ($900 - $1000)	T	.	$950.00	.	$190.00
1549	New Technology - Level XII ($1000 - $1100)	T	.	$1,050.00	.	$210.00
1550	New Technology - Level XIII ($1100 - $1200)	T	.	$1,150.00	.	$230.00
1551	New Technology - Level XIV ($1200-$1300)	T	.	$1,250.00	.	$250.00
1552	New Technology - Level XV ($1300 - $1400)	T	.	$1,350.00	.	$270.00
1553	New Technology - Level XVI ($1400 - $1500)	T	.	$1,450.00	.	$290.00
1554	New Technology - Level XVII ($1500-$1600)	T	.	$1,550.00	.	$310.00
1555	New Technology - Level XVIII ($1600-$1700)	T	.	$1,650.00	.	$330.00
1556	New Technology - Level XIX ($1700-$1800)	T	.	$1,750.00	.	$350.00
1557	New Technology - Level XX ($1800-$1900)	T	.	$1,850.00	.	$370.00
1558	New Technology - Level XXI ($1900-$2000)	T	.	$1,950.00	.	$390.00
1559	New Technology - Level XXII ($2000-	T	.	$2,250.00	.	$450.00

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
	$2500)					
1560	New Technology - Level XXIII ($2500-$3000)	T	.	$2,750.00	.	$550.00
1561	New Technology - Level XXIV ($3000-$3500)	T	.	$3,250.00	.	$650.00
1562	New Technology - Level XXV ($3500-$4000)	T	.	$3,750.00	.	$750.00
1563	New Technology - Level XXVI ($4000-$4500)	T	.	$4,250.00	.	$850.00
1564	New Technology - Level XXVII ($4500-$5000)	T	.	$4,750.00	.	$950.00
1565	New Technology - Level XXVIII ($5000-$5500)	T	.	$5,250.00	.	$1,050.00
1566	New Technology - Level XXIX ($5500-$6000)	T	.	$5,750.00	.	$1,150.00
1567	New Technology - Level XXX ($6000-$6500)	T	.	$6,250.00	.	$1,250.00
1568	New Technology - Level XXXI ($6500-$7000)	T	.	$6,750.00	.	$1,350.00
1569	New Technology - Level XXXII ($7000-$7500)	T	.	$7,250.00	.	$1,450.00
1570	New Technology - Level XXXIII ($7500-$8000)	T	.	$7,750.00	.	$1,550.00
1571	New Technology - Level XXXIV ($8000-$8500)	T	.	$8,250.00	.	$1,650.00
1572	New Technology - Level XXXV ($8500-$9000)	T	.	$8,750.00	.	$1,750.00
1573	New Technology - Level XXXVI ($9000-$9500)	T	.	$9,250.00	.	$1,850.00
1574	New Technology - Level XXXVII ($9500-$10000)	T	.	$9,750.00	.	$1,950.00
1605	Abciximab injection	K	.	$433.69	.	$86.74
1607	Eptifibatide injection	K	.	$17.55	.	$3.51
1608	Etanercept injection	K	.	$170.59	.	$34.12
1609	Rho(D) immune globulin h, sd	K	.	$16.49	.	$3.30
1612	Daclizumab, parenteral	K	.	$338.05	.	$67.61
1613	Trastuzumab injection	K	.	$60.33	.	$12.07
1630	Hep b ig, im	K	.	$121.53	.	$24.31
1631	Baclofen intrathecal trial	K	.	$68.14	.	$13.63
1633	Alefacept	K	.	$27.81	.	$5.57
1643	Y90 ibritumomab, rx	H	.		.	.
1645	I131 tositumomab, rx	H	.		.	.
1670	Tetanus immune globulin inj	K	.	$134.95	.	$26.99
1675	P32 Na phosphate	H	.		.	.

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
1676	P32 chromic phosphate	H	.		.	.
1682	Aprotonin, 10,000 kiu	K	.	$2.60	.	$0.52
1683	Basiliximab	K	.	$1,565.52	.	$313.11
1684	Corticorelin ovine triflutal	K	.	$4.31	.	$0.87
1685	Darbepoetin alfa, non-esrd	K	.	$2.91	.	$0.59
1686	Epoetin alfa, non-esrd	K	.	$8.92	.	$1.79
1687	Digoxin immune fab (ovine)	K	.	$484.63	.	$96.93
1688	Ethanolamine oleate	K	.	$147.14	.	$29.43
1689	Fomepizole	K	.	$11.63	.	$2.33
1690	Hemin	K	.	$7.45	.	$1.49
1693	Lepirudin	K	.	$173.32	.	$34.67
1694	Ziconotide injection	K	.	$6.37	.	$1.28
1695	Nesiritide injection	K	.	$33.91	.	$6.79
1696	Palifermin injection	K	.	$11.18	.	$2.24
1697	Pegaptanib sodium injection	K	.	$1,002.76	.	$200.56
1700	Inj secretin synthetic human	K	.	$19.93	.	$3.99
1701	Treprostinil injection	K	.	$55.95	.	$11.19
1703	Ovine, 1000 USP units	K	.	$130.62	.	$26.13
1704	Humate-P, inj	K	.	$0.86	.	$0.18
1705	Factor viia	K	.	$1.21	.	$0.25
1709	Azacitidine injection	K	.	$4.50	.	$0.90
1710	Clofarabine injection	K	.	$113.61	.	$22.73
1711	Vantas implant	G	.	$1,430.40	.	$280.68
1712	Paclitaxel protein bound	K	.	$8.63	.	$1.73
1716	Brachytx, non-str, Gold-198	U	.			
1717	Brachytx, non-str, HDR Ir-192	U	.			
1719	Brachytx, NS, Non-HDRIr-192	U	.			
1738	Oxaliplatin	K	.	$9.38	.	$1.88
1739	Pegademase bovine, 25 iu	K	.	$221.87	.	$44.38
1740	Diazoxide injection	K	.	$112.16	.	$22.44
1741	Urofollitropin, 75 iu	K	.	$50.03	.	$10.01
2210	Methyldopate hcl injection	K	.	$12.39	.	$2.48
2616	Brachytx, non-str,Yttrium-90	U	.			
2632	Iodine I-125 sodium iodide	U	.			
2634	Brachytx, non-str, HA, I-125	U	.			
2635	Brachytx, non-str, HA, P-103	U	.			
2636	Brachy linear, non-str,P-103	U	.			
2638	Brachytx, stranded, I-125	U	.			
2639	Brachytx, non-stranded,I-125	U	.			
2640	Brachytx, stranded, P-103	U	.			
2641	Brachytx, non-stranded,P-103	U	.			

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
2642	Brachytx, stranded, C-131	U	.			
2643	Brachytx, non-stranded,C-131	U	.			
2698	Brachytx, stranded, NOS	U	.			
2699	Brachytx, non-stranded, NOS	U	.			
2731	Immune globulin, powder	K	.	$28.68	.	$5.74
2770	Quinupristin/dalfopristin	K	.	$137.14	.	$27.43
3030	Sumatriptan succinate	K	.	$71.21	.	$14.25
3041	Bivalirudin	K	.	$2.30	.	$0.46
3043	Gamma globulin 1 CC inj	K	.	$11.87	.	$2.38
3050	Sermorelin acetate injection	K	.	$1.71	.	$0.35
7000	Amifostine	K	.	$416.03	.	$83.21
7005	Gonadorelin hydroch	K	.	$176.89	.	$35.38
7011	Oprelvekin injection	K	.	$242.00	.	$48.40
7015	Oral busulfan	K	.	$2.74	.	$0.55
7034	Somatropin injection	K	.	$49.82	.	$9.97
7035	Teniposide	K	.	$297.01	.	$59.41
7036	Urokinase 250,000 IU inj	K	.	$449.09	.	$89.82
7038	Monoclonal antibodies	K	.	$1,083.34	.	$216.67
7041	Tirofiban HCl	K	.	$7.18	.	$1.44
7042	Capecitabine, oral	K	.	$4.82	.	$0.97
7043	Infliximab injection	K	.	$56.00	.	$11.20
7045	Inj trimetrexate glucoronate	K	.	$146.89	.	$29.38
7046	Doxorubicin hcl liposome inj	K	.	$421.41	.	$84.29
7048	Alteplase recombinant	K	.	$32.26	.	$6.46
7049	Filgrastim 480 mcg injection	K	.	$301.43	.	$60.29
7051	Leuprolide acetate implant	K	.	$1,661.45	.	$332.29
7308	Aminolevulinic acid hcl top	K	.	$115.29	.	$23.06
8000	Cardiac Electrophysiologic Evaluation and Ablation Composite	T	142.5732	$9,418.24	.	$1,883.65
8001	LDR Prostate Brachytherapy Composite	T	45.9446	$3,035.05	.	$607.01
8002	Level I Extended Assessment & Management Composite	V	5.6874	$375.70	.	$75.14
8003	Level II Extended Assessment & Management Composite	V	10.2140	$674.73	.	$134.95
8004	Ultrasound Composite	S	2.9170	$192.69	.	$38.54
8005	CT and CTA without Contrast Composite	S	6.2937	$415.76	.	$83.16
8006	CT and CTA with Contrast Composite	S	9.6142	$635.10	.	$127.02
8007	MRI and MRA without Contrast Composite	S	10.7639	$711.05	.	$142.21
8008	MRI and MRA with Contrast Composite	S	14.9915	$990.32	.	$198.07
9001	Linezolid injection	K	.	$28.18	.	$5.64
9002	Tenecteplase injection	K	.	$1,929.45	.	$385.89

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
9003	Palivizumab	K	.	$882.44	.	$176.49
9004	Gemtuzumab ozogamicin inj	K	.	$2,448.21	.	$489.65
9005	Reteplase injection	K	.	$828.27	.	$165.66
9006	Tacrolimus injection	K	.	$136.97	.	$27.40
9012	Arsenic trioxide injection	K	.	$33.88	.	$6.78
9015	Mycophenolate mofetil oral	K	.	$3.09	.	$0.62
9018	Botulinum toxin type B	K	.	$8.94	.	$1.79
9019	Caspofungin acetate	K	.	$14.47	.	$2.90
9020	Sirolimus, oral	K	.	$8.24	.	$1.65
9022	IM inj interferon beta 1-a	K	.	$143.90	.	$28.78
9023	Rho d immune globulin	K	.	$26.36	.	$5.28
9024	Amphotericin b lipid complex	K	.	$10.05	.	$2.01
9032	Baclofen 10 MG injection	K	.	$184.28	.	$36.86
9033	Cidofovir injection	K	.	$747.70	.	$149.54
9038	Inj estrogen conjugate	K	.	$74.17	.	$14.84
9042	Glucagon hydrochloride	K	.	$71.40	.	$14.28
9044	Ibutilide fumarate injection	K	.	$364.11	.	$72.83
9046	Iron sucrose injection	K	.	$0.36	.	$0.08
9047	Itraconazole injection	K	.	$36.84	.	$7.37
9104	Antithymocyte globuln rabbit	K	.	$365.31	.	$73.07
9108	Thyrotropin injection	K	.	$961.31	.	$192.27
9110	Alemtuzumab injection	K	.	$540.84	.	$108.17
9115	Zoledronic acid	K	.	$210.02	.	$42.01
9119	Injection, pegfilgrastim 6mg	K	.	$2,155.11	.	$431.03
9120	Injection, Fulvestrant	K	.	$79.70	.	$15.94
9121	Injection, argatroban	K	.	$19.87	.	$3.98
9122	Triptorelin pamoate	K	.	$149.61	.	$29.93
9124	Daptomycin injection	K	.	$0.37	.	$0.08
9125	Risperidone, long acting	K	.	$4.86	.	$0.98
9126	Natalizumab injection	K	.	$7.44	.	$1.49
9133	Rabies ig, im/sc	K	.	$89.18	.	$17.84
9134	Rabies ig, heat treated	K	.	$96.22	.	$19.25
9135	Varicella-zoster ig, im	K	.	$109.88	.	$21.98
9137	Bcg vaccine, percut	K	.	$115.88	.	$23.18
9139	Rabies vaccine, im	K	.	$144.11	.	$28.83
9140	Rabies vaccine, id	K		$112.29	.	$22.46
9143	Meningococcal vaccine, sc	K	.	$92.09	.	$18.42
9145	Meningococcal vaccine, im	K	.	$80.46	.	$16.10
9207	Bortezomib injection	K	.	$34.68	.	$6.94
9208	Agalsidase beta injection	K	.	$128.54	.	$25.71
9209	Laronidase injection	K	.	$24.14	.	$4.83

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
9210	Palonosetron hcl	K	.	$16.13	.	$3.23
9213	Pemetrexed injection	K	.	$46.40	.	$9.28
9214	Bevacizumab injection	K	.	$56.29	.	$11.26
9215	Cetuximab injection	K	.	$48.82	.	$9.77
9216	Abarelix injection	K	.	$67.32	.	$13.47
9217	Leuprolide acetate suspnsion	K	.	$169.68	.	$33.94
9219	Mycophenolic acid	K	.	$2.56	.	$0.52
9224	Galsulfase injection	K	.	$325.95	.	$65.19
9225	Fluocinolone acetonide implt	K	.	$18,980.00	.	$3,796.00
9227	Micafungin sodium injection	K	.	$1.24	.	$0.25
9228	Tigecycline injection	K	.	$1.09	.	$0.22
9229	Ibandronate sodium injection	K	.	$137.65	.	$27.53
9230	Abatacept injection	K	.	$18.51	.	$3.71
9231	Decitabine injection	K	.	$26.23	.	$5.25
9232	Idursulfase injection	K	.	$450.71	.	$90.15
9233	Ranibizumab injection	K	.	$402.31	.	$80.47
9234	Alglucosidase alfa injection	K	.	$124.80	.	$24.96
9235	Panitumumab injection	K	.	$80.93	.	$16.19
9236	Eculizumab injection	G	.	$176.38	.	$34.61
9237	Inj, lanreotide acetate	K	.	$26.21	.	$5.25
9238	Inj, levetiracetam	G	.	$0.41	.	$0.08
9240	Injection, ixabepilone	G	.	$65.15	.	$12.78
9241	Injection, doripenem	G	.	$0.65	.	$0.13
9242	Injection, fosaprepitant	G	.	$1.57	.	$0.31
9243	Bendamustine injection	G	.	$18.70	.	$3.67
9244	Regadenoson injection	G	.	$214.49	.	$42.09
9245	Injection, romiplostim	G	.	$45.05	.	$8.84
9246	Inj, gadoxetate disodium	G	.	$13.78	.	$2.70
9248	Inj, clevidipine butyrate	G	.	$6.15	.	$1.21
9300	Omalizumab injection	K	.	$17.79	.	$3.56
9354	Veritas collagen matrix, cm2	G	.	$11.18	.	$2.19
9355	Neuromatrix nerve cuff, cm	G	.	$212.46	.	$41.69
9356	TenoGlide tendon prot, cm2	G	.	$28.32	.	$5.56
9358	SurgiMend, 0.5cm2	G	.	$10.55	.	$2.07
9359	Implant, bone void filler	G	.	$56.71	.	$11.13
9500	Platelets, irradiated	R	2.4890	$164.42	.	$32.89
9501	Platelet pheres leukoreduced	R	7.7934	$514.82	.	$102.97
9502	Platelet pheresis irradiated	R	7.1078	$469.53	.	$93.91
9503	Fr frz plasma donor retested	R	0.9726	$64.25	.	$12.85
9504	RBC deglycerolized	R	5.1685	$341.43	.	$68.29
9505	RBC irradiated	R	3.7950	$250.69	.	$50.14

ADDENDUM A.--FINAL OPPS APCs FOR CY 2009						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
9506	Granulocytes, pheresis unit	R	25.2803	$1,669.99	.	$334.00
9507	Platelets, pheresis	R	7.0946	$468.66	.	$93.74
9508	Plasma 1 donor frz w/in 8 hr	R	1.1615	$76.73	.	$15.35

ADDENDUM AA.--FINAL ASC COVERED SURGICAL PROCEDURES FOR CY 2009 (INCLUDING SURGICAL PROCEDURES FOR WHICH PAYMENT IS PACKAGED)

ADDENDUM AA.--FINAL ASC COVERED SURGICAL PROCEDURES FOR CY 2009 (INCLUDING SURGICAL PROCEDURES FOR WHICH PAYMENT IS PACKAGED)						
HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
0016T	Thermotx choroid vasc lesion	Y		R2	5.6826	$235.22
0017T	Photocoagulat macular drusen	Y		R2	5.6826	$235.22
0027T	Endoscopic epidural lysis	N	CH	D5		
0031T	Speculoscopy	N	CH	D5		
0032T	Speculoscopy w/direct sample	N	CH	D5		
0046T	Cath lavage, mammary duct(s)	N	CH	D5		
0047T	Cath lavage, mammary duct(s)	N	CH	D5		
0084T*	Temp prostate urethral stent	Y	CH	R2	1.8231	$75.46
0088T	Rf tongue base vol reduxn	N	CH	D5		
0099T*	Implant corneal ring	Y		R2	16.3241	$675.70
0100T	Prosth retina receive&gen	Y		G2	37.2245	$1,540.83
0101T	Extracorp shockwv tx,hi enrg	Y		G2	29.1375	$1,206.09
0102T	Extracorp shockwv tx,anesth	Y		G2	29.1375	$1,206.09
0123T	Scleral fistulization	Y		G2	23.3013	$964.51
0124T*	Conjunctival drug placement	Y		R2	4.5545	$188.52
0137T	Prostate saturation sampling	N	CH	D5		
0170T	Anorectal fistula plug rpr	Y		G2	30.2669	$1,252.84
0176T	Aqu canal dilat w/o retent	Y		A2	35.7384	$1,479.32
0177T	Aqu canal dilat w retent	Y		A2	35.7384	$1,479.32
0186T	Suprachoroidal drug delivery	Y		G2	21.771	$901.17
0190T	Place intraoc radiation src	Y		G2	21.771	$901.17
0191T	Insert ant segment drain int	Y		G2	23.3013	$964.51
0192T	Insert ant segment drain ext	Y		G2	39.9338	$1,652.98
10021	Fna w/o image	Y		P2	1.3967	$57.81
10022	Fna w/image	Y		G2	4.3613	$180.53
10040	Acne surgery	Y		P2	0.8075	$33.42
10060	Drainage of skin abscess	Y		P3	1.2285	$50.85
10061	Drainage of skin abscess	Y		P2	1.3776	$57.02
10080	Drainage of pilonidal cyst	Y		P2	1.3776	$57.02
10081	Drainage of pilonidal cyst	Y		P3	3.1716	$131.28
10120	Remove foreign body	Y	CH	P3	1.7252	$71.41
10121	Remove foreign body	Y		A2	13.0039	$538.27
10140	Drainage of hematoma/fluid	Y		P3	1.8298	$75.74
10160	Puncture drainage of lesion	Y		P2	1.3776	$57.02

NOTE: The Medicare program payment is 80 percent of the total payment amount and beneficiary coinsurance is 20 percent of the total payment amount, except for screening flexible sigmoidoscopies and screening colonoscopies for which the program payment is 75 percent and the beneficiary coinsurance is 25 percent.

*Refers to codes designated as "office-based," whose designation as office-based is temporary because we have insufficient claims data. We will reconsider this designation when new claims data become available.

ADDENDUM AA.--FINAL ASC COVERED SURGICAL PROCEDURES FOR CY 2009 (INCLUDING SURGICAL PROCEDURES FOR WHICH PAYMENT IS PACKAGED)						
HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
10180	Complex drainage, wound	Y		A2	14.7056	$608.71
11000	Debride infected skin	Y		P3	0.5926	$24.53
11001	Debride infected skin add-on	Y		P3	0.2005	$8.30
11010	Debride skin, fx	Y		A2	5.1448	$212.96
11011	Debride skin/muscle, fx	Y		A2	5.1448	$212.96
11012	Debride skin/muscle/bone, fx	Y		A2	5.1448	$212.96
11040	Debride skin, partial	Y		P3	0.5402	$22.36
11041	Debride skin, full	Y		P3	0.6013	$24.89
11042	Debride skin/tissue	Y		A2	3.267	$135.23
11043	Debride tissue/muscle	Y		A2	3.267	$135.23
11044	Debride tissue/muscle/bone	Y		A2	8.5068	$352.12
11055	Trim skin lesion	Y		P3	0.6361	$26.33
11056	Trim skin lesions, 2 to 4	Y		P3	0.697	$28.85
11057	Trim skin lesions, over 4	Y	CH	P2	0.8075	$33.42
11100	Biopsy, skin lesion	Y		P2	1.4792	$61.23
11101	Biopsy, skin add-on	Y		P3	0.3486	$14.43
11200	Removal of skin tags	Y		P2	0.8075	$33.42
11201	Remove skin tags add-on	Y		P3	0.1394	$5.77
11300	Shave skin lesion	Y		P2	0.8075	$33.42
11301	Shave skin lesion	Y		P2	0.8075	$33.42
11302	Shave skin lesion	Y		P2	0.8075	$33.42
11303	Shave skin lesion	Y		P2	1.4792	$61.23
11305	Shave skin lesion	Y		P2	0.8075	$33.42
11306	Shave skin lesion	Y		P2	0.8075	$33.42
11307	Shave skin lesion	Y		P2	0.8075	$33.42
11308	Shave skin lesion	Y		P2	0.8075	$33.42
11310	Shave skin lesion	Y		P2	0.8075	$33.42
11311	Shave skin lesion	Y		P2	0.8075	$33.42
11312	Shave skin lesion	Y		P2	0.8075	$33.42
11313	Shave skin lesion	Y		P2	0.8075	$33.42
11400	Exc tr-ext b9+marg 0.5 < cm	Y		P3	1.6643	$68.89
11401	Exc tr-ext b9+marg 0.6-1 cm	Y		P3	1.8733	$77.54
11402	Exc tr-ext b9+marg 1.1-2 cm	Y		P3	2.0564	$85.12
11403	Exc tr-ext b9+marg 2.1-3 cm	Y		P3	2.1958	$90.89
11404	Exc tr-ext b9+marg 3.1-4 cm	Y		A2	11.673	$483.18
11406	Exc tr-ext b9+marg > 4.0 cm	Y		A2	13.0039	$538.27
11420	Exc h-f-nk-sp b9+marg 0.5 <	Y		P3	1.5597	$64.56
11421	Exc h-f-nk-sp b9+marg 0.6-1	Y		P3	1.8907	$78.26

NOTE: The Medicare program payment is 80 percent of the total payment amount and beneficiary coinsurance is 20 percent of the total payment amount, except for screening flexible sigmoidoscopies and screening colonoscopies for which the program payment is 75 percent and the beneficiary coinsurance is 25 percent.

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ADDENDUM AA.--FINAL ASC COVERED SURGICAL PROCEDURES FOR CY 2009 (INCLUDING SURGICAL PROCEDURES FOR WHICH PAYMENT IS PACKAGED)						
HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
11422	Exc h-f-nk-sp b9+marg 1.1-2	Y		P3	2.0651	$85.48
11423	Exc h-f-nk-sp b9+marg 2.1-3	Y		P3	2.3004	$95.22
11424	Exc h-f-nk-sp b9+marg 3.1-4	Y		A2	13.0039	$538.27
11426	Exc h-f-nk-sp b9+marg > 4 cm	Y		A2	15.9027	$658.26
11440	Exc face-mm b9+marg 0.5 < cm	Y		P3	1.7863	$73.94
11441	Exc face-mm b9+marg 0.6-1 cm	Y		P3	2.0651	$85.48
11442	Exc face-mm b9+marg 1.1-2 cm	Y		P3	2.2741	$94.13
11443	Exc face-mm b9+marg 2.1-3 cm	Y		P3	2.5181	$104.23
11444	Exc face-mm b9+marg 3.1-4 cm	Y		A2	7.9477	$328.98
11446	Exc face-mm b9+marg > 4 cm	Y		A2	15.9027	$658.26
11450	Removal, sweat gland lesion	Y		A2	15.9027	$658.26
11451	Removal, sweat gland lesion	Y		A2	15.9027	$658.26
11462	Removal, sweat gland lesion	Y		A2	15.9027	$658.26
11463	Removal, sweat gland lesion	Y		A2	15.9027	$658.26
11470	Removal, sweat gland lesion	Y		A2	15.9027	$658.26
11471	Removal, sweat gland lesion	Y		A2	15.9027	$658.26
11600	Exc tr-ext mlg+marg 0.5 < cm	Y		P3	2.3439	$97.02
11601	Exc tr-ext mlg+marg 0.6-1 cm	Y		P3	2.8406	$117.58
11602	Exc tr-ext mlg+marg 1.1-2 cm	Y		P3	3.1281	$129.48
11603	Exc tr-ext mlg+marg 2.1-3 cm	Y		P3	3.3196	$137.41
11604	Exc tr-ext mlg+marg 3.1-4 cm	Y		A2	8.9547	$370.66
11606	Exc tr-ext mlg+marg > 4 cm	Y		A2	13.0039	$538.27
11620	Exc h-f-nk-sp mlg+marg 0.5 <	Y		P3	2.4224	$100.27
11621	Exc h-f-nk-sp mlg+marg 0.6-1	Y		P3	2.8754	$119.02
11622	Exc h-f-nk-sp mlg+marg 1.1-2	Y		P3	3.1976	$132.36
11623	Exc h-f-nk-sp mlg+marg 2.1-3	Y		P3	3.4416	$142.46
11624	Exc h-f-nk-sp mlg+marg 3.1-4	Y		A2	13.0039	$538.27
11626	Exc h-f-nk-sp mlg+mar > 4 cm	Y		A2	15.9027	$658.26
11640	Exc face-mm malig+marg 0.5 <	Y		P3	2.5618	$106.04
11641	Exc face-mm malig+marg 0.6-1	Y		P3	3.0235	$125.15
11642	Exc face-mm malig+marg 1.1-2	Y		P3	3.3721	$139.58
11643	Exc face-mm malig+marg 2.1-3	Y		P3	3.6335	$150.40
11644	Exc face-mm malig+marg 3.1-4	Y		A2	13.0039	$538.27
11646	Exc face-mm mlg+marg > 4 cm	Y		A2	15.9027	$658.26
11719	Trim nail(s)	Y		P3	0.2962	$12.26
11720	Debride nail, 1-5	Y		P3	0.366	$15.15
11721	Debride nail, 6 or more	Y		P3	0.4443	$18.39
11730	Removal of nail plate	Y		P2	0.8075	$33.42

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HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
11732	Remove nail plate, add-on	Y		P3	0.4443	$18.39
11740	Drain blood from under nail	Y		P2	0.4079	$16.88
11750	Removal of nail bed	Y		P3	2.3526	$97.38
11752	Remove nail bed/finger tip	Y		P3	3.2675	$135.25
11755	Biopsy, nail unit	Y		P3	1.6293	$67.44
11760	Repair of nail bed	Y		G2	3.3557	$138.90
11762	Reconstruction of nail bed	Y		P3	2.9974	$124.07
11765	Excision of nail fold, toe	Y		P2	0.8075	$33.42
11770	Removal of pilonidal lesion	Y		A2	16.6567	$689.47
11771	Removal of pilonidal lesion	Y		A2	16.6567	$689.47
11772	Removal of pilonidal lesion	Y		A2	16.6567	$689.47
11900	Injection into skin lesions	Y		P3	0.7407	$30.66
11901	Added skin lesions injection	Y	CH	P2	0.8075	$33.42
11920	Correct skin color defects	Y	CH	P3	2.3439	$97.02
11921	Correct skin color defects	Y	CH	P3	2.5792	$106.76
11922	Correct skin color defects	Y		P3	0.8364	$34.62
11950	Therapy for contour defects	Y		P3	0.854	$35.35
11951	Therapy for contour defects	Y		P3	1.063	$44.00
11952	Therapy for contour defects	Y		P2	1.2797	$52.97
11954	Therapy for contour defects	Y		P2	1.2797	$52.97
11960	Insert tissue expander(s)	Y		A2	15.5239	$642.58
11970	Replace tissue expander	Y		A2	28.119	$1,163.93
11971	Remove tissue expander(s)	Y		A2	14.5718	$603.17
11976	Removal of contraceptive cap	Y		P3	1.5597	$64.56
11980	Implant hormone pellet(s)	N		P2	0.6301	$26.08
11981	Insert drug implant device	N		P2	0.6301	$26.08
11982	Remove drug implant device	N		P2	0.6301	$26.08
11983	Remove/insert drug implant	N		P2	0.6301	$26.08
12001	Repair superficial wound(s)	Y		P2	1.2797	$52.97
12002	Repair superficial wound(s)	Y		P2	1.2797	$52.97
12004	Repair superficial wound(s)	Y		P2	1.2797	$52.97
12005	Repair superficial wound(s)	Y		A2	1.7145	$70.97
12006	Repair superficial wound(s)	Y		A2	1.7145	$70.97
12007	Repair superficial wound(s)	Y		A2	1.7145	$70.97
12011	Repair superficial wound(s)	Y		P2	1.2797	$52.97
12013	Repair superficial wound(s)	Y		P2	1.2797	$52.97
12014	Repair superficial wound(s)	Y		P2	1.2797	$52.97
12015	Repair superficial wound(s)	Y		G2	1.2797	$52.97

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12016	Repair superficial wound(s)	Y		A2	1.7145	$70.97
12017	Repair superficial wound(s)	Y		A2	1.7145	$70.97
12018	Repair superficial wound(s)	Y		A2	1.7145	$70.97
12020	Closure of split wound	Y		A2	3.2348	$133.90
12021	Closure of split wound	Y		A2	2.7524	$113.93
12031	Intmd wnd repair s/tr/ext	Y		P2	1.2797	$52.97
12032	Intmd wnd repair s/tr/ext	Y		P2	3.3557	$138.90
12034	Intmd wnd repair s/tr/ext	Y		A2	1.7145	$70.97
12035	Intmd wnd repair s/tr/ext	Y		A2	1.7145	$70.97
12036	Intmd wnd repair s/tr/ext	Y		A2	2.7524	$113.93
12037	Intmd wnd repair s/tr/ext	Y		A2	5.4857	$227.07
12041	Intmd wnd repair n-hf/genit	Y		P2	1.2797	$52.97
12042	Intmd wnd repair n-hg/genit	Y		P2	1.2797	$52.97
12044	Intmd wnd repair n-hg/genit	Y		A2	1.7145	$70.97
12045	Intmd wnd repair n-hg/genit	Y		A2	2.7524	$113.93
12046	Intmd wnd repair n-hg/genit	Y		A2	2.7524	$113.93
12047	Intmd wnd repair n-hg/genit	Y		A2	5.4857	$227.07
12051	Intmd wnd repair face/mm	Y		P2	1.2797	$52.97
12052	Intmd wnd repair face/mm	Y		P2	1.2797	$52.97
12053	Intmd wnd repair face/mm	Y		P2	1.2797	$52.97
12054	Intmd wnd repair, face/mm	Y		A2	1.7145	$70.97
12055	Intmd wnd repair face/mm	Y		A2	2.7524	$113.93
12056	Intmd wnd repair face/mm	Y		A2	2.7524	$113.93
12057	Intmd wnd repair face/mm	Y		A2	5.4857	$227.07
13100	Repair of wound or lesion	Y		A2	5.9679	$247.03
13101	Repair of wound or lesion	Y		A2	5.9679	$247.03
13102	Repair wound/lesion add-on	Y		A2	3.2348	$133.90
13120	Repair of wound or lesion	Y		A2	2.7524	$113.93
13121	Repair of wound or lesion	Y		A2	2.7524	$113.93
13122	Repair wound/lesion add-on	Y		A2	2.7524	$113.93
13131	Repair of wound or lesion	Y		A2	2.7524	$113.93
13132	Repair of wound or lesion	Y		A2	2.7524	$113.93
13133	Repair wound/lesion add-on	Y		A2	2.7524	$113.93
13150	Repair of wound or lesion	Y		A2	5.9679	$247.03
13151	Repair of wound or lesion	Y		A2	5.9679	$247.03
13152	Repair of wound or lesion	Y		A2	5.9679	$247.03
13153	Repair wound/lesion add-on	Y		A2	2.7524	$113.93
13160	Late closure of wound	Y		A2	15.5239	$642.58

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14000	Skin tissue rearrangement	Y		A2	13.0418	$539.84
14001	Skin tissue rearrangement	Y		A2	13.7956	$571.04
14020	Skin tissue rearrangement	Y		A2	13.7956	$571.04
14021	Skin tissue rearrangement	Y		A2	13.7956	$571.04
14040	Skin tissue rearrangement	Y		A2	13.0418	$539.84
14041	Skin tissue rearrangement	Y		A2	13.7956	$571.04
14060	Skin tissue rearrangement	Y		A2	13.7956	$571.04
14061	Skin tissue rearrangement	Y		A2	13.7956	$571.04
14300	Skin tissue rearrangement	Y		A2	17.6912	$732.29
14350	Skin tissue rearrangement	Y		A2	16.2776	$673.78
15002	Wound prep, trk/arm/leg	Y		A2	5.9679	$247.03
15003	Wound prep, addl 100 cm	Y		A2	5.9679	$247.03
15004	Wound prep, f/n/hf/g	Y		A2	5.9679	$247.03
15005	Wnd prep, f/n/hf/g, addl cm	Y		A2	5.9679	$247.03
15040	Harvest cultured skin graft	Y		A2	2.7524	$113.93
15050	Skin pinch graft	Y		A2	5.9679	$247.03
15100	Skin splt grft, trnk/arm/leg	Y		A2	15.5239	$642.58
15101	Skin splt grft t/a/l, add-on	Y		A2	16.2776	$673.78
15110	Epidrm autogrft trnk/arm/leg	Y		A2	7.4133	$306.86
15111	Epidrm autogrft t/a/l add-on	Y		A2	6.0824	$251.77
15115	Epidrm a-grft face/nck/hf/g	Y		A2	7.4133	$306.86
15116	Epidrm a-grft f/n/hf/g addl	Y		A2	6.0824	$251.77
15120	Skn splt a-grft fac/nck/hf/g	Y		A2	15.5239	$642.58
15121	Skn splt a-grft f/n/hf/g add	Y		A2	16.2776	$673.78
15130	Derm autograft, trnk/arm/leg	Y		A2	13.0418	$539.84
15131	Derm autograft t/a/l add-on	Y		A2	11.7107	$484.74
15135	Derm autograft face/nck/hf/g	Y		A2	13.0418	$539.84
15136	Derm autograft, f/n/hf/g add	Y		A2	11.7107	$484.74
15150	Cult epiderm grft t/arm/leg	Y		A2	7.4133	$306.86
15151	Cult epiderm grft t/a/l addl	Y		A2	6.0824	$251.77
15152	Cult epiderm graft t/a/l +%	Y		A2	6.0824	$251.77
15155	Cult epiderm graft, f/n/hf/g	Y		A2	7.4133	$306.86
15156	Cult epidrm grft f/n/hfg add	Y		A2	6.0824	$251.77
15157	Cult epiderm grft f/n/hfg +%	Y		A2	6.0824	$251.77
15170	Acell graft trunk/arms/legs	Y	CH	G2	3.3557	$138.90
15171	Acell graft t/arm/leg add-on	Y	CH	G2	3.3557	$138.90
15175	Acellular graft, f/n/hf/g	Y	CH	G2	4.3203	$178.83
15176	Acell graft, f/n/hf/g add-on	Y	CH	G2	4.3203	$178.83

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HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
15200	Skin full graft, trunk	Y		A2	13.7956	$571.04
15201	Skin full graft trunk add-on	Y		A2	11.5964	$480.01
15220	Skin full graft sclp/arm/leg	Y		A2	13.0418	$539.84
15221	Skin full graft add-on	Y		A2	5.9679	$247.03
15240	Skin full grft face/genit/hf	Y		A2	13.7956	$571.04
15241	Skin full graft add-on	Y		A2	5.9679	$247.03
15260	Skin full graft een & lips	Y		A2	13.0418	$539.84
15261	Skin full graft add-on	Y		A2	11.5964	$480.01
15300	Apply skinallogrft, t/arm/lg	Y		A2	5.9679	$247.03
15301	Apply sknallogrft t/a/l addl	Y		A2	5.9679	$247.03
15320	Apply skin allogrft f/n/hf/g	Y		A2	5.9679	$247.03
15321	Aply sknallogrft f/n/hfg add	Y		A2	5.9679	$247.03
15330	Aply acell alogrft t/arm/leg	Y		A2	5.9679	$247.03
15331	Aply acell grft t/a/l add-on	Y		A2	5.9679	$247.03
15335	Apply acell graft, f/n/hf/g	Y		A2	5.9679	$247.03
15336	Aply acell grft f/n/hf/g add	Y		A2	5.9679	$247.03
15340	Apply cult skin substitute	Y		G2	3.3557	$138.90
15341	Apply cult skin sub add-on	Y		G2	3.3557	$138.90
15360	Apply cult derm sub, t/a/l	Y		G2	3.3557	$138.90
15361	Aply cult derm sub t/a/l add	Y		G2	3.3557	$138.90
15365	Apply cult derm sub f/n/hf/g	Y		G2	3.3557	$138.90
15366	Apply cult derm f/hf/g add	Y		G2	3.3557	$138.90
15400	Apply skin xenograft, t/a/l	Y		A2	5.9679	$247.03
15401	Apply skn xenogrft t/a/l add	Y		A2	5.9679	$247.03
15420	Apply skin xgraft, f/n/hf/g	Y		A2	5.9679	$247.03
15421	Apply skn xgrft f/n/hf/g add	Y		A2	5.9679	$247.03
15430	Apply acellular xenograft	Y		A2	5.9679	$247.03
15431	Apply acellular xgraft add	Y		A2	5.9679	$247.03
15570	Form skin pedicle flap	Y		A2	16.2776	$673.78
15572	Form skin pedicle flap	Y		A2	16.2776	$673.78
15574	Form skin pedicle flap	Y		A2	16.2776	$673.78
15576	Form skin pedicle flap	Y		A2	16.2776	$673.78
15600	Skin graft	Y		A2	16.2776	$673.78
15610	Skin graft	Y		A2	16.2776	$673.78
15620	Skin graft	Y		A2	17.6912	$732.29
15630	Skin graft	Y		A2	16.2776	$673.78
15650	Transfer skin pedicle flap	Y		A2	18.7157	$774.70
15731	Forehead flap w/vasc pedicle	Y		A2	16.2776	$673.78

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15732	Muscle-skin graft, head/neck	Y		A2	16.2776	$673.78
15734	Muscle-skin graft, trunk	Y		A2	16.2776	$673.78
15736	Muscle-skin graft, arm	Y		A2	16.2776	$673.78
15738	Muscle-skin graft, leg	Y		A2	16.2776	$673.78
15740	Island pedicle flap graft	Y		A2	13.0418	$539.84
15750	Neurovascular pedicle graft	Y		A2	15.5239	$642.58
15760	Composite skin graft	Y		A2	15.5239	$642.58
15770	Derma-fat-fascia graft	Y		A2	16.2776	$673.78
15775	Hair transplant punch grafts	Y		A2	4.4476	$184.10
15776	Hair transplant punch grafts	Y		A2	4.4476	$184.10
15780	Abrasion treatment of skin	Y		P3	9.9157	$410.44
15781	Abrasion treatment of skin	Y		P2	4.3646	$180.66
15782	Abrasion treatment of skin	Y		P2	4.3646	$180.66
15783	Abrasion treatment of skin	Y		P2	2.6609	$110.14
15786	Abrasion, lesion, single	Y		P2	0.8075	$33.42
15787	Abrasion, lesions, add-on	Y	CH	P3	0.732	$30.30
15788	Chemical peel, face, epiderm	Y		P2	0.8075	$33.42
15789	Chemical peel, face, dermal	Y		P2	1.4792	$61.23
15792	Chemical peel, nonfacial	Y		P2	1.4792	$61.23
15793	Chemical peel, nonfacial	Y		P2	0.8075	$33.42
15819	Plastic surgery, neck	Y		G2	3.3557	$138.90
15820	Revision of lower eyelid	Y		A2	16.2776	$673.78
15821	Revision of lower eyelid	Y		A2	16.2776	$673.78
15822	Revision of upper eyelid	Y		A2	16.2776	$673.78
15823	Revision of upper eyelid	Y		A2	18.7157	$774.70
15824	Removal of forehead wrinkles	Y		A2	16.2776	$673.78
15825	Removal of neck wrinkles	Y		A2	16.2776	$673.78
15826	Removal of brow wrinkles	Y		A2	16.2776	$673.78
15828	Removal of face wrinkles	Y		A2	16.2776	$673.78
15829	Removal of skin wrinkles	Y		A2	18.7157	$774.70
15830	Exc skin abd	Y		A2	16.6567	$689.47
15832	Excise excessive skin tissue	Y		A2	16.6567	$689.47
15833	Excise excessive skin tissue	Y		A2	16.6567	$689.47
15834	Excise excessive skin tissue	Y		A2	16.6567	$689.47
15835	Excise excessive skin tissue	Y		A2	14.4573	$598.43
15836	Excise excessive skin tissue	Y		A2	13.7579	$569.48
15837	Excise excessive skin tissue	Y		G2	15.5016	$641.66
15838	Excise excessive skin tissue	Y		G2	15.5016	$641.66

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15839	Excise excessive skin tissue	Y		A2	13.7579	$569.48
15840	Graft for face nerve palsy	Y		A2	17.6912	$732.29
15841	Graft for face nerve palsy	Y		A2	17.6912	$732.29
15842	Flap for face nerve palsy	Y		G2	20.5411	$850.26
15845	Skin and muscle repair, face	Y		A2	17.6912	$732.29
15847	Exc skin abd add-on	Y		A2	16.6567	$689.47
15850	Removal of sutures	Y		G2	2.6609	$110.14
15851	Removal of sutures	Y		P3	1.2111	$50.13
15852	Dressing change not for burn	N		G2	0.6301	$26.08
15860	Test for blood flow in graft	N		G2	0.6301	$26.08
15876	Suction assisted lipectomy	Y		A2	16.2776	$673.78
15877	Suction assisted lipectomy	Y		A2	16.2776	$673.78
15878	Suction assisted lipectomy	Y		A2	16.2776	$673.78
15879	Suction assisted lipectomy	Y		A2	16.2776	$673.78
15920	Removal of tail bone ulcer	Y		A2	5.1448	$212.96
15922	Removal of tail bone ulcer	Y		A2	17.6912	$732.29
15931	Remove sacrum pressure sore	Y		A2	16.6567	$689.47
15933	Remove sacrum pressure sore	Y		A2	16.6567	$689.47
15934	Remove sacrum pressure sore	Y		A2	16.2776	$673.78
15935	Remove sacrum pressure sore	Y		A2	17.6912	$732.29
15936	Remove sacrum pressure sore	Y		A2	15.2091	$629.55
15937	Remove sacrum pressure sore	Y		A2	17.6912	$732.29
15940	Remove hip pressure sore	Y		A2	16.6567	$689.47
15941	Remove hip pressure sore	Y		A2	16.6567	$689.47
15944	Remove hip pressure sore	Y		A2	16.2776	$673.78
15945	Remove hip pressure sore	Y		A2	17.6912	$732.29
15946	Remove hip pressure sore	Y		A2	17.6912	$732.29
15950	Remove thigh pressure sore	Y		A2	16.6567	$689.47
15951	Remove thigh pressure sore	Y		A2	18.07	$747.97
15952	Remove thigh pressure sore	Y		A2	13.7956	$571.04
15953	Remove thigh pressure sore	Y		A2	15.2091	$629.55
15956	Remove thigh pressure sore	Y		A2	13.7956	$571.04
15958	Remove thigh pressure sore	Y		A2	15.2091	$629.55
16000	Initial treatment of burn(s)	Y		P3	0.6535	$27.05
16020	Dress/debrid p-thick burn, s	Y		P3	0.9934	$41.12
16025	Dress/debrid p-thick burn, m	Y		A2	1.53	$63.33
16030	Dress/debrid p-thick burn, l	Y		A2	1.9155	$79.29
16035	Incision of burn scab, initi	Y		G2	1.4792	$61.23

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HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
17000	Destruct premalg lesion	Y		P2	0.8075	$33.42
17003	Destruct premalg les, 2-14	Y		P3	0.0959	$3.97
17004	Destroy premlg lesions 15+	Y		P3	2.1086	$87.28
17106	Destruction of skin lesions	Y		P2	2.6609	$110.14
17107	Destruction of skin lesions	Y		P2	2.6609	$110.14
17108	Destruction of skin lesions	Y		P2	2.6609	$110.14
17110	Destruct b9 lesion, 1-14	Y		P2	0.8075	$33.42
17111	Destruct lesion, 15 or more	Y		P2	1.4792	$61.23
17250	Chemical cautery, tissue	Y		P3	1.1154	$46.17
17260	Destruction of skin lesions	Y		P3	1.1937	$49.41
17261	Destruction of skin lesions	Y		P2	1.4792	$61.23
17262	Destruction of skin lesions	Y		P2	1.4792	$61.23
17263	Destruction of skin lesions	Y		P2	1.4792	$61.23
17264	Destruction of skin lesions	Y		P2	1.4792	$61.23
17266	Destruction of skin lesions	Y		P2	2.6609	$110.14
17270	Destruction of skin lesions	Y		P2	1.4792	$61.23
17271	Destruction of skin lesions	Y		P2	1.4792	$61.23
17272	Destruction of skin lesions	Y		P2	1.4792	$61.23
17273	Destruction of skin lesions	Y	CH	P2	2.6609	$110.14
17274	Destruction of skin lesions	Y		P2	2.6609	$110.14
17276	Destruction of skin lesions	Y		P2	2.6609	$110.14
17280	Destruction of skin lesions	Y		P2	1.4792	$61.23
17281	Destruction of skin lesions	Y		P3	2.2045	$91.25
17282	Destruction of skin lesions	Y		P3	2.5181	$104.23
17283	Destruction of skin lesions	Y		P2	2.6609	$110.14
17284	Destruction of skin lesions	Y		P2	2.6609	$110.14
17286	Destruction of skin lesions	Y		P2	2.6609	$110.14
17311	Mohs, 1 stage, h/n/hf/g	Y		P2	4.3925	$181.82
17312	Mohs addl stage	Y		P2	4.3925	$181.82
17313	Mohs, 1 stage, t/a/l	Y		P2	4.3925	$181.82
17314	Mohs, addl stage, t/a/l	Y		P2	4.3925	$181.82
17315	Mohs surg, addl block	Y		P3	0.9934	$41.12
17340	Cryotherapy of skin	Y		P3	0.3573	$14.79
17360	Skin peel therapy	Y		P2	0.8075	$33.42
17380	Hair removal by electrolysis	Y		R2	0.8075	$33.42
19000	Drainage of breast lesion	Y		P3	1.6817	$69.61
19001	Drain breast lesion add-on	Y		P3	0.2266	$9.38
19020	Incision of breast lesion	Y		A2	14.7056	$608.71

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19030	Injection for breast x-ray	N		N1		
19100	Bx breast percut w/o image	Y		A2	5.0076	$207.28
19101	Biopsy of breast, open	Y		A2	15.7283	$651.04
19102	Bx breast percut w/image	Y		A2	6.4289	$266.11
19103	Bx breast percut w/device	Y		A2	11.2521	$465.76
19105	Cryosurg ablate fa, each	Y		G2	32.7384	$1,355.14
19110	Nipple exploration	Y		A2	15.7283	$651.04
19112	Excise breast duct fistula	Y		A2	16.4823	$682.25
19120	Removal of breast lesion	Y		A2	16.4823	$682.25
19125	Excision, breast lesion	Y		A2	16.4823	$682.25
19126	Excision, addl breast lesion	Y		A2	16.4823	$682.25
19290	Place needle wire, breast	N		N1		
19291	Place needle wire, breast	N		N1		
19295	Place breast clip, percut	N		N1		
19296	Place po breast cath for rad	Y		A2	45.0813	$1,866.05
19297	Place breast cath for rad	Y		A2	45.0813	$1,866.05
19298	Place breast rad tube/caths	Y		A2	45.0813	$1,866.05
19300	Removal of breast tissue	Y		A2	17.8955	$740.75
19301	Partical mastectomy	Y		A2	16.4823	$682.25
19302	P-mastectomy w/ln removal	Y		A2	31.4792	$1,303.02
19303	Mast, simple, complete	Y		A2	23.7898	$984.73
19304	Mast, subq	Y		A2	23.7898	$984.73
19316	Suspension of breast	Y		A2	23.7898	$984.73
19318	Reduction of large breast	Y		A2	27.18	$1,125.06
19324	Enlarge breast	Y		A2	27.18	$1,125.06
19325	Enlarge breast with implant	Y		A2	45.0813	$1,866.05
19328	Removal of breast implant	Y		A2	20.2916	$839.93
19330	Removal of implant material	Y		A2	20.2916	$839.93
19340	Immediate breast prosthesis	Y		A2	25.0127	$1,035.35
19342	Delayed breast prosthesis	Y		A2	35.3168	$1,461.87
19350	Breast reconstruction	Y		A2	17.8955	$740.75
19355	Correct inverted nipple(s)	Y		A2	23.7898	$984.73
19357	Breast reconstruction	Y		A2	37.7549	$1,562.79
19366	Breast reconstruction	Y		A2	24.8146	$1,027.15
19370	Surgery of breast capsule	Y		A2	23.7898	$984.73
19371	Removal of breast capsule	Y		A2	23.7898	$984.73
19380	Revise breast reconstruction	Y		A2	28.2048	$1,167.48
19396	Design custom breast implant	Y		G2	32.7384	$1,355.14

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20000	Incision of abscess	Y		P2	1.3776	$57.02
20005	Incision of deep abscess	Y		A2	15.8725	$657.01
20103	Explore wound, extremity	Y		G2	15.5772	$644.79
20150	Excise epiphyseal bar	Y		G2	44.2241	$1,830.57
20200	Muscle biopsy	Y		A2	13.0039	$538.27
20205	Deep muscle biopsy	Y		A2	13.7579	$569.48
20206	Needle biopsy, muscle	Y		A2	6.4289	$266.11
20220	Bone biopsy, trocar/needle	Y		A2	6.9881	$289.26
20225	Bone biopsy, trocar/needle	Y		A2	12.6799	$524.86
20240	Bone biopsy, excisional	Y		A2	15.9027	$658.26
20245	Bone biopsy, excisional	Y		A2	16.6567	$689.47
20250	Open bone biopsy	Y		A2	16.6265	$688.22
20251	Open bone biopsy	Y		A2	16.6265	$688.22
20500	Injection of sinus tract	Y		P3	1.3768	$56.99
20501	Inject sinus tract for x-ray	N		N1		
20520	Removal of foreign body	Y		P3	2.3178	$95.94
20525	Removal of foreign body	Y		A2	16.6567	$689.47
20526	Ther injection, carp tunnel	Y		P3	0.7494	$31.02
20550	Inj tendon sheath/ligament	Y		P3	0.5663	$23.44
20551	Inj tendon origin/insertion	Y		P3	0.5576	$23.08
20552	Inj trigger point, 1/2 muscl	Y		P3	0.5402	$22.36
20553	Inject trigger points, =/> 3	Y		P3	0.6013	$24.89
20555	Place ndl musc/tis for rt	Y		G2	29.1375	$1,206.09
20600	Drain/inject, joint/bursa	Y		P3	0.575	$23.80
20605	Drain/inject, joint/bursa	Y		P3	0.6448	$26.69
20610	Drain/inject, joint/bursa	Y		P3	0.9062	$37.51
20612	Aspirate/inj ganglion cyst	Y		P3	0.61	$25.25
20615	Treatment of bone cyst	Y		P3	2.5531	$105.68
20650	Insert and remove bone pin	Y		A2	16.6265	$688.22
20662	Application of pelvis brace	Y		R2	21.2387	$879.13
20663	Application of thigh brace	Y		R2	21.2387	$879.13
20665	Removal of fixation device	N		G2	0.6301	$26.08
20670	Removal of support implant	Y		A2	11.673	$483.18
20680	Removal of support implant	Y		A2	16.6567	$689.47
20690	Apply bone fixation device	Y		A2	19.822	$820.49
20692	Apply bone fixation device	Y		A2	20.5759	$851.70
20693	Adjust bone fixation device	Y		A2	16.6265	$688.22
20694	Remove bone fixation device	Y		A2	14.5416	$601.92

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20696	Comp multiplane ext fixation	Y	NI	G2	29.1375	$1,206.09
20697	Comp ext fixate strut change	Y	NI	G2	19.3776	$802.10
20822	Replantation digit, complete	Y		G2	27.3022	$1,130.12
20900	Removal of bone for graft	Y		A2	20.5759	$851.70
20902	Removal of bone for graft	Y		A2	21.9892	$910.20
20910	Remove cartilage for graft	Y		A2	16.2776	$673.78
20912	Remove cartilage for graft	Y		A2	16.2776	$673.78
20920	Removal of fascia for graft	Y		A2	15.2091	$629.55
20922	Removal of fascia for graft	Y		A2	13.7956	$571.04
20924	Removal of tendon for graft	Y		A2	21.9892	$910.20
20926	Removal of tissue for graft	Y		A2	9.5806	$396.57
20950	Fluid pressure, muscle	Y		G2	1.3776	$57.02
20972	Bone/skin graft, metatarsal	Y		G2	46.114	$1,908.80
20973	Bone/skin graft, great toe	Y		R2	46.114	$1,908.80
20975	Electrical bone stimulation	N		N1		
20979	Us bone stimulation	N	CH	P3	0.5663	$23.44
20982	Ablate, bone tumor(s) perq	Y		G2	44.2241	$1,830.57
20985	Cptr-asst dir ms px	N		N1		
20986	Cptr-asst dir ms px io img	N	CH	D5		
20987	Cptr-asst dir ms px pre img	N	CH	D5		
21010	Incision of jaw joint	Y		A2	17.3227	$717.04
21015	Resection of facial tumor	Y		A2	14.4126	$596.58
21025	Excision of bone, lower jaw	Y		A2	25.6688	$1,062.51
21026	Excision of facial bone(s)	Y		A2	25.6688	$1,062.51
21029	Contour of face bone lesion	Y		A2	25.6688	$1,062.51
21030	Excise max/zygoma b9 tumor	Y		P3	6.0556	$250.66
21031	Remove exostosis, mandible	Y		P3	5.01	$207.38
21032	Remove exostosis, maxilla	Y		P3	5.1059	$211.35
21034	Excise max/zygoma mlg tumor	Y		A2	26.4228	$1,093.72
21040	Excise mandible lesion	Y		A2	17.3227	$717.04
21044	Removal of jaw bone lesion	Y		A2	25.6688	$1,062.51
21046	Remove mandible cyst complex	Y		A2	25.6688	$1,062.51
21047	Excise lwr jaw cyst w/repair	Y		A2	25.6688	$1,062.51
21048	Remove maxilla cyst complex	Y		R2	40.8314	$1,690.13
21050	Removal of jaw joint	Y		A2	26.4228	$1,093.72
21060	Remove jaw joint cartilage	Y		A2	25.6688	$1,062.51
21070	Remove coronoid process	Y		A2	26.4228	$1,093.72
21073*	Mnpj of tmj w/anesth	Y		P3	4.7051	$194.76

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21076	Prepare face/oral prosthesis	Y		P3	8.1642	$337.94
21077	Prepare face/oral prosthesis	Y		P3	19.7355	$816.91
21079	Prepare face/oral prosthesis	Y		P3	14.1328	$585.00
21080	Prepare face/oral prosthesis	Y		P3	16.2066	$670.84
21081	Prepare face/oral prosthesis	Y		P3	14.9344	$618.18
21082	Prepare face/oral prosthesis	Y		P3	14.2113	$588.25
21083	Prepare face/oral prosthesis	Y		P3	14.0021	$579.59
21084	Prepare face/oral prosthesis	Y		P3	16.1107	$666.87
21085	Prepare face/oral prosthesis	Y		P3	6.3955	$264.73
21086	Prepare face/oral prosthesis	Y		P3	13.9236	$576.34
21087	Prepare face/oral prosthesis	Y		P3	13.9412	$577.07
21088	Prepare face/oral prosthesis	Y		R2	40.8314	$1,690.13
21100	Maxillofacial fixation	Y		A2	25.6688	$1,062.51
21110	Interdental fixation	Y		P2	7.3454	$304.05
21116	Injection, jaw joint x-ray	N		N1		
21120	Reconstruction of chin	Y		A2	23.7893	$984.71
21121	Reconstruction of chin	Y		A2	23.7893	$984.71
21122	Reconstruction of chin	Y		A2	23.7893	$984.71
21123	Reconstruction of chin	Y		A2	23.7893	$984.71
21125	Augmentation, lower jaw bone	Y		A2	23.7893	$984.71
21127	Augmentation, lower jaw bone	Y		A2	36.187	$1,497.89
21137	Reduction of forehead	Y		G2	24.1393	$999.20
21138	Reduction of forehead	Y		G2	40.8314	$1,690.13
21139	Reduction of forehead	Y		G2	40.8314	$1,690.13
21150	Reconstruct midface, lefort	Y		G2	40.8314	$1,690.13
21181	Contour cranial bone lesion	Y		A2	23.7893	$984.71
21198	Reconstr lwr jaw segment	Y		G2	40.8314	$1,690.13
21199	Reconstr lwr jaw w/advance	Y		G2	40.8314	$1,690.13
21206	Reconstruct upper jaw bone	Y		A2	28.8609	$1,194.64
21208	Augmentation of facial bones	Y		A2	32.1354	$1,330.18
21209	Reduction of facial bones	Y		A2	28.8609	$1,194.64
21210	Face bone graft	Y		A2	32.1354	$1,330.18
21215	Lower jaw bone graft	Y		A2	32.1354	$1,330.18
21230	Rib cartilage graft	Y		A2	32.1354	$1,330.18
21235	Ear cartilage graft	Y		A2	23.7893	$984.71
21240	Reconstruction of jaw joint	Y		A2	27.8361	$1,152.22
21242	Reconstruction of jaw joint	Y		A2	28.8609	$1,194.64
21243	Reconstruction of jaw joint	Y		A2	28.8609	$1,194.64

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21244	Reconstruction of lower jaw	Y		A2	32.1354	$1,330.18
21245	Reconstruction of jaw	Y		A2	32.1354	$1,330.18
21246	Reconstruction of jaw	Y		A2	32.1354	$1,330.18
21248	Reconstruction of jaw	Y		A2	32.1354	$1,330.18
21249	Reconstruction of jaw	Y		A2	32.1354	$1,330.18
21260	Revise eye sockets	Y		G2	40.8314	$1,690.13
21267	Revise eye sockets	Y		A2	32.1354	$1,330.18
21270	Augmentation, cheek bone	Y		A2	28.8609	$1,194.64
21275	Revision, orbitofacial bones	Y		A2	32.1354	$1,330.18
21280	Revision of eyelid	Y		A2	28.8609	$1,194.64
21282	Revision of eyelid	Y		A2	16.8507	$697.50
21295	Revision of jaw muscle/bone	Y		A2	7.595	$314.38
21296	Revision of jaw muscle/bone	Y		A2	15.9918	$661.95
21310	Treatment of nose fracture	Y		A2	2.3168	$95.90
21315	Treatment of nose fracture	Y		A2	10.1807	$421.41
21320	Treatment of nose fracture	Y		A2	13.6586	$565.37
21325	Treatment of nose fracture	Y		A2	19.49	$806.75
21330	Treatment of nose fracture	Y		A2	20.5148	$849.17
21335	Treatment of nose fracture	Y		A2	23.7893	$984.71
21336	Treat nasal septal fracture	Y		A2	19.8258	$820.65
21337	Treat nasal septal fracture	Y		A2	13.6586	$565.37
21338	Treat nasoethmoid fracture	Y		A2	19.49	$806.75
21339	Treat nasoethmoid fracture	Y		A2	20.5148	$849.17
21340	Treatment of nose fracture	Y		A2	27.8361	$1,152.22
21345	Treat nose/jaw fracture	Y		A2	23.7893	$984.71
21355	Treat cheek bone fracture	Y		A2	26.4228	$1,093.72
21356	Treat cheek bone fracture	Y		A2	18.0767	$748.25
21360	Treat cheek bone fracture	Y		G2	24.1393	$999.20
21390	Treat eye socket fracture	Y		G2	40.8314	$1,690.13
21400	Treat eye socket fracture	Y		A2	8.9259	$369.47
21401	Treat eye socket fracture	Y		A2	14.4126	$596.58
21406	Treat eye socket fracture	Y		G2	40.8314	$1,690.13
21407	Treat eye socket fracture	Y		G2	40.8314	$1,690.13
21421	Treat mouth roof fracture	Y		A2	19.49	$806.75
21440	Treat dental ridge fracture	Y		P3	8.2079	$339.75
21445	Treat dental ridge fracture	Y		A2	19.49	$806.75
21450	Treat lower jaw fracture	Y		A2	3.3875	$140.22
21451	Treat lower jaw fracture	Y		A2	9.1397	$378.32

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21452	Treat lower jaw fracture	Y		A2	13.6586	$565.37
21453	Treat lower jaw fracture	Y		A2	26.4228	$1,093.72
21454	Treat lower jaw fracture	Y		A2	20.5148	$849.17
21461	Treat lower jaw fracture	Y		A2	27.8361	$1,152.22
21462	Treat lower jaw fracture	Y		A2	28.8609	$1,194.64
21465	Treat lower jaw fracture	Y		A2	27.8361	$1,152.22
21480	Reset dislocated jaw	Y		A2	2.3168	$95.90
21485	Reset dislocated jaw	Y		A2	13.6586	$565.37
21490	Repair dislocated jaw	Y		A2	26.4228	$1,093.72
21495	Treat hyoid bone fracture	Y		G2	16.8109	$695.85
21497	Interdental wiring	Y		A2	13.6586	$565.37
21501	Drain neck/chest lesion	Y		A2	14.7056	$608.71
21502	Drain chest lesion	Y		A2	15.8725	$657.01
21550	Biopsy of neck/chest	Y		G2	15.5016	$641.66
21555	Remove lesion, neck/chest	Y		A2	15.9027	$658.26
21556	Remove lesion, neck/chest	Y		A2	15.9027	$658.26
21557	Remove tumor, neck/chest	Y		G2	21.299	$881.63
21600	Partial removal of rib	Y		A2	19.822	$820.49
21610	Partial removal of rib	Y		A2	19.822	$820.49
21685	Hyoid myotomy & suspension	Y		G2	7.3454	$304.05
21700	Revision of neck muscle	Y		A2	15.8725	$657.01
21720	Revision of neck muscle	Y		A2	16.6265	$688.22
21725	Revision of neck muscle	Y		A2	1.7307	$71.64
21800	Treatment of rib fracture	Y		A2	1.9994	$82.76
21805	Treatment of rib fracture	Y		A2	17.6585	$730.94
21820	Treat sternum fracture	Y		A2	1.9994	$82.76
21920	Biopsy soft tissue of back	Y		P3	3.5549	$147.15
21925	Biopsy soft tissue of back	Y		A2	15.9027	$658.26
21930	Remove lesion, back or flank	Y		A2	15.9027	$658.26
21935	Remove tumor, back	Y		A2	16.6567	$689.47
22102	Remove part, lumbar vertebra	Y		G2	47.3966	$1,961.89
22103	Remove extra spine segment	Y		G2	47.3966	$1,961.89
22305	Treat spine process fracture	Y		A2	1.9994	$82.76
22310	Treat spine fracture	Y		A2	4.2179	$174.59
22315	Treat spine fracture	Y		A2	10.9093	$451.57
22505	Manipulation of spine	Y		A2	12.843	$531.61
22520	Percut vertebroplasty thor	Y		A2	30.3402	$1,255.87
22521	Percut vertebroplasty lumb	Y		A2	30.3402	$1,255.87

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HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
22522	Percut vertebroplasty add'l	Y		A2	30.3402	$1,255.87
22523	Percut kyphoplasty, thor	Y		G2	84.4396	$3,495.21
22524	Percut kyphoplasty, lumbar	Y		G2	84.4396	$3,495.21
22525	Percut kyphoplasty, add-on	Y		G2	84.4396	$3,495.21
22900	Remove abdominal wall lesion	Y		A2	18.07	$747.97
23000	Removal of calcium deposits	Y		A2	13.0039	$538.27
23020	Release shoulder joint	Y		A2	27.3653	$1,132.73
23030	Drain shoulder lesion	Y		A2	13.3745	$553.61
23031	Drain shoulder bursa	Y		A2	15.4594	$639.91
23035	Drain shoulder bone lesion	Y		A2	16.6265	$688.22
23040	Exploratory shoulder surgery	Y		A2	20.5759	$851.70
23044	Exploratory shoulder surgery	Y		A2	21.9892	$910.20
23065	Biopsy shoulder tissues	Y		P3	2.4572	$101.71
23066	Biopsy shoulder tissues	Y		A2	15.9027	$658.26
23075	Removal of shoulder lesion	Y		A2	13.0039	$538.27
23076	Removal of shoulder lesion	Y		A2	15.9027	$658.26
23077	Remove tumor of shoulder	Y		A2	16.6567	$689.47
23100	Biopsy of shoulder joint	Y		A2	15.8725	$657.01
23101	Shoulder joint surgery	Y		A2	26.2885	$1,088.16
23105	Remove shoulder joint lining	Y		A2	21.9892	$910.20
23106	Incision of collarbone joint	Y		A2	21.9892	$910.20
23107	Explore treat shoulder joint	Y		A2	21.9892	$910.20
23120	Partial removal, collar bone	Y		A2	23.014	$952.62
23125	Removal of collar bone	Y		A2	23.014	$952.62
23130	Remove shoulder bone, part	Y		A2	30.5571	$1,264.85
23140	Removal of bone lesion	Y		A2	18.0398	$746.72
23145	Removal of bone lesion	Y		A2	23.014	$952.62
23146	Removal of bone lesion	Y		A2	23.014	$952.62
23150	Removal of humerus lesion	Y		A2	21.9892	$910.20
23155	Removal of humerus lesion	Y		A2	23.014	$952.62
23156	Removal of humerus lesion	Y		A2	23.014	$952.62
23170	Remove collar bone lesion	Y		A2	19.822	$820.49
23172	Remove shoulder blade lesion	Y		A2	19.822	$820.49
23174	Remove humerus lesion	Y		A2	19.822	$820.49
23180	Remove collar bone lesion	Y		A2	21.9892	$910.20
23182	Remove shoulder blade lesion	Y		A2	21.9892	$910.20
23184	Remove humerus lesion	Y		A2	21.9892	$910.20
23190	Partial removal of scapula	Y		A2	21.9892	$910.20

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23195	Removal of head of humerus	Y		A2	23.014	$952.62
23330	Remove shoulder foreign body	Y		A2	7.9477	$328.98
23331	Remove shoulder foreign body	Y		A2	14.5718	$603.17
23350	Injection for shoulder x-ray	N		N1		
23395	Muscle transfer,shoulder/arm	Y		A2	30.5571	$1,264.85
23397	Muscle transfers	Y		A2	53.9396	$2,232.72
23400	Fixation of shoulder blade	Y		A2	26.2885	$1,088.16
23405	Incision of tendon & muscle	Y		A2	19.822	$820.49
23406	Incise tendon(s) & muscle(s)	Y		A2	19.822	$820.49
23410	Repair rotator cuff, acute	Y		A2	30.5571	$1,264.85
23412	Repair rotator cuff, chronic	Y		A2	33.8316	$1,400.39
23415	Release of shoulder ligament	Y		A2	30.5571	$1,264.85
23420	Repair of shoulder	Y		A2	33.8316	$1,400.39
23430	Repair biceps tendon	Y		A2	29.5325	$1,222.44
23440	Remove/transplant tendon	Y		A2	29.5325	$1,222.44
23450	Repair shoulder capsule	Y		A2	50.6651	$2,097.18
23455	Repair shoulder capsule	Y		A2	53.9396	$2,232.72
23460	Repair shoulder capsule	Y		A2	50.6651	$2,097.18
23462	Repair shoulder capsule	Y		A2	33.8316	$1,400.39
23465	Repair shoulder capsule	Y		A2	50.6651	$2,097.18
23466	Repair shoulder capsule	Y		A2	33.8316	$1,400.39
23480	Revision of collar bone	Y		A2	29.5325	$1,222.44
23485	Revision of collar bone	Y		A2	53.9396	$2,232.72
23490	Reinforce clavicle	Y		A2	28.119	$1,163.93
23491	Reinforce shoulder bones	Y		A2	48.227	$1,996.26
23500	Treat clavicle fracture	Y		A2	1.9994	$82.76
23505	Treat clavicle fracture	Y		A2	10.9093	$451.57
23515	Treat clavicle fracture	Y		A2	36.5127	$1,511.37
23520	Treat clavicle dislocation	Y		A2	4.2179	$174.59
23525	Treat clavicle dislocation	Y		A2	4.2179	$174.59
23530	Treat clavicle dislocation	Y		A2	26.9062	$1,113.73
23532	Treat clavicle dislocation	Y		A2	19.8258	$820.65
23540	Treat clavicle dislocation	Y		A2	1.9994	$82.76
23545	Treat clavicle dislocation	Y		A2	4.2179	$174.59
23550	Treat clavicle dislocation	Y		A2	26.9062	$1,113.73
23552	Treat clavicle dislocation	Y		A2	28.3198	$1,172.24
23570	Treat shoulder blade fx	Y		A2	1.9994	$82.76
23575	Treat shoulder blade fx	Y		A2	4.2179	$174.59

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23585	Treat scapula fracture	Y		A2	36.5127	$1,511.37
23600	Treat humerus fracture	Y		P2	1.5579	$64.49
23605	Treat humerus fracture	Y		A2	10.9093	$451.57
23615	Treat humerus fracture	Y		A2	37.926	$1,569.87
23616	Treat humerus fracture	Y		A2	37.926	$1,569.87
23620	Treat humerus fracture	Y		P2	1.5579	$64.49
23625	Treat humerus fracture	Y		A2	10.9093	$451.57
23630	Treat humerus fracture	Y		A2	38.9508	$1,612.29
23650	Treat shoulder dislocation	Y		A2	1.9994	$82.76
23655	Treat shoulder dislocation	Y		A2	11.5121	$476.52
23660	Treat shoulder dislocation	Y		A2	26.9062	$1,113.73
23665	Treat dislocation/fracture	Y		A2	4.2179	$174.59
23670	Treat dislocation/fracture	Y		A2	36.5127	$1,511.37
23675	Treat dislocation/fracture	Y		A2	1.9994	$82.76
23680	Treat dislocation/fracture	Y		A2	26.9062	$1,113.73
23700	Fixation of shoulder	Y		A2	11.5121	$476.52
23800	Fusion of shoulder joint	Y		A2	49.6403	$2,054.76
23802	Fusion of shoulder joint	Y		A2	33.8316	$1,400.39
23921	Amputation follow-up surgery	Y		A2	11.5964	$480.01
23930	Drainage of arm lesion	Y		A2	13.3745	$553.61
23931	Drainage of arm bursa	Y		A2	14.7056	$608.71
23935	Drain arm/elbow bone lesion	Y		A2	15.8725	$657.01
24000	Exploratory elbow surgery	Y		A2	21.9892	$910.20
24006	Release elbow joint	Y		A2	21.9892	$910.20
24065	Biopsy arm/elbow soft tissue	Y		P3	3.4069	$141.02
24066	Biopsy arm/elbow soft tissue	Y		A2	13.0039	$538.27
24075	Remove arm/elbow lesion	Y		A2	13.0039	$538.27
24076	Remove arm/elbow lesion	Y		A2	15.9027	$658.26
24077	Remove tumor of arm/elbow	Y		A2	16.6567	$689.47
24100	Biopsy elbow joint lining	Y		A2	14.5416	$601.92
24101	Explore/treat elbow joint	Y		A2	21.9892	$910.20
24102	Remove elbow joint lining	Y		A2	21.9892	$910.20
24105	Removal of elbow bursa	Y		A2	16.6265	$688.22
24110	Remove humerus lesion	Y		A2	15.8725	$657.01
24115	Remove/graft bone lesion	Y		A2	20.5759	$851.70
24116	Remove/graft bone lesion	Y		A2	20.5759	$851.70
24120	Remove elbow lesion	Y		A2	16.6265	$688.22
24125	Remove/graft bone lesion	Y		A2	20.5759	$851.70

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24126	Remove/graft bone lesion	Y		A2	20.5759	$851.70
24130	Removal of head of radius	Y		A2	20.5759	$851.70
24134	Removal of arm bone lesion	Y		A2	19.822	$820.49
24136	Remove radius bone lesion	Y		A2	19.822	$820.49
24138	Remove elbow bone lesion	Y		A2	19.822	$820.49
24140	Partial removal of arm bone	Y		A2	20.5759	$851.70
24145	Partial removal of radius	Y		A2	20.5759	$851.70
24147	Partial removal of elbow	Y		A2	19.822	$820.49
24149	Radical resection of elbow	Y		G2	29.1375	$1,206.09
24152	Extensive radius surgery	Y		G2	44.2241	$1,830.57
24153	Extensive radius surgery	Y		G2	84.4396	$3,495.21
24155	Removal of elbow joint	Y		A2	28.119	$1,163.93
24160	Remove elbow joint implant	Y		A2	19.822	$820.49
24164	Remove radius head implant	Y		A2	20.5759	$851.70
24200	Removal of arm foreign body	Y		P3	2.492	$103.15
24201	Removal of arm foreign body	Y		A2	13.0039	$538.27
24220	Injection for elbow x-ray	N		N1		
24300	Manipulate elbow w/anesth	Y		G2	15.1797	$628.33
24301	Muscle/tendon transfer	Y		A2	21.9892	$910.20
24305	Arm tendon lengthening	Y		A2	21.9892	$910.20
24310	Revision of arm tendon	Y		A2	16.6265	$688.22
24320	Repair of arm tendon	Y		A2	28.119	$1,163.93
24330	Revision of arm muscles	Y		A2	48.227	$1,996.26
24331	Revision of arm muscles	Y		A2	28.119	$1,163.93
24332	Tenolysis, triceps	Y		G2	21.2387	$879.13
24340	Repair of biceps tendon	Y		A2	28.119	$1,163.93
24341	Repair arm tendon/muscle	Y		A2	28.119	$1,163.93
24342	Repair of ruptured tendon	Y		A2	28.119	$1,163.93
24343	Repr elbow lat ligmnt w/tiss	Y		G2	29.1375	$1,206.09
24344	Reconstruct elbow lat ligmnt	Y		G2	84.4396	$3,495.21
24345	Repr elbw med ligmnt w/tissu	Y		A2	19.822	$820.49
24346	Reconstruct elbow med ligmnt	Y		G2	44.2241	$1,830.57
24357	Repair elbow, perc	Y		G2	29.1375	$1,206.09
24358	Repair elbow w/deb, open	Y		G2	29.1375	$1,206.09
24359	Repair elbow deb/attch open	Y		G2	29.1375	$1,206.09
24360	Reconstruct elbow joint	Y		A2	26.8898	$1,113.05
24361	Reconstruct elbow joint	Y	CH	H8	147.0205	$6,085.62
24362	Reconstruct elbow joint	Y		A2	34.365	$1,422.47

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24363	Replace elbow joint	Y	CH	H8	150.295	$6,221.16
24365	Reconstruct head of radius	Y		A2	26.8898	$1,113.05
24366	Reconstruct head of radius	Y	CH	H8	147.0205	$6,085.62
24400	Revision of humerus	Y		A2	21.9892	$910.20
24410	Revision of humerus	Y		A2	21.9892	$910.20
24420	Revision of humerus	Y		A2	28.119	$1,163.93
24430	Repair of humerus	Y		A2	48.227	$1,996.26
24435	Repair humerus with graft	Y		A2	49.6403	$2,054.76
24470	Revision of elbow joint	Y		A2	28.119	$1,163.93
24495	Decompression of forearm	Y		A2	19.822	$820.49
24498	Reinforce humerus	Y		A2	48.227	$1,996.26
24500	Treat humerus fracture	Y		A2	1.9994	$82.76
24505	Treat humerus fracture	Y		A2	1.9994	$82.76
24515	Treat humerus fracture	Y		A2	37.926	$1,569.87
24516	Treat humerus fracture	Y		A2	37.926	$1,569.87
24530	Treat humerus fracture	Y		A2	1.9994	$82.76
24535	Treat humerus fracture	Y		A2	4.2179	$174.59
24538	Treat humerus fracture	Y		A2	17.6585	$730.94
24545	Treat humerus fracture	Y		A2	37.926	$1,569.87
24546	Treat humerus fracture	Y		A2	38.9508	$1,612.29
24560	Treat humerus fracture	Y		A2	1.9994	$82.76
24565	Treat humerus fracture	Y		A2	1.9994	$82.76
24566	Treat humerus fracture	Y		A2	17.6585	$730.94
24575	Treat humerus fracture	Y		A2	36.5127	$1,511.37
24576	Treat humerus fracture	Y		A2	1.9994	$82.76
24577	Treat humerus fracture	Y		A2	4.2179	$174.59
24579	Treat humerus fracture	Y		A2	36.5127	$1,511.37
24582	Treat humerus fracture	Y		A2	17.6585	$730.94
24586	Treat elbow fracture	Y		A2	37.926	$1,569.87
24587	Treat elbow fracture	Y		A2	38.9508	$1,612.29
24600	Treat elbow dislocation	Y		A2	1.9994	$82.76
24605	Treat elbow dislocation	Y		A2	12.843	$531.61
24615	Treat elbow dislocation	Y		A2	36.5127	$1,511.37
24620	Treat elbow fracture	Y		A2	10.9093	$451.57
24635	Treat elbow fracture	Y		A2	36.5127	$1,511.37
24640	Treat elbow dislocation	Y		P3	1.3505	$55.90
24650	Treat radius fracture	Y		P2	1.5579	$64.49
24655	Treat radius fracture	Y		A2	4.2179	$174.59

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24665	Treat radius fracture	Y		A2	28.3198	$1,172.24
24666	Treat radius fracture	Y		A2	37.926	$1,569.87
24670	Treat ulnar fracture	Y		A2	1.9994	$82.76
24675	Treat ulnar fracture	Y		A2	1.9994	$82.76
24685	Treat ulnar fracture	Y		A2	26.9062	$1,113.73
24800	Fusion of elbow joint	Y		A2	29.5325	$1,222.44
24802	Fusion/graft of elbow joint	Y		A2	30.5571	$1,264.85
24925	Amputation follow-up surgery	Y		A2	16.6265	$688.22
25000	Incision of tendon sheath	Y		A2	16.6265	$688.22
25001	Incise flexor carpi radialis	Y		G2	21.2387	$879.13
25020	Decompress forearm 1 space	Y		A2	16.6265	$688.22
25023	Decompress forearm 1 space	Y		A2	20.5759	$851.70
25024	Decompress forearm 2 spaces	Y		A2	20.5759	$851.70
25025	Decompress forearm 2 spaces	Y		A2	20.5759	$851.70
25028	Drainage of forearm lesion	Y		A2	14.5416	$601.92
25031	Drainage of forearm bursa	Y		A2	15.8725	$657.01
25035	Treat forearm bone lesion	Y		A2	15.8725	$657.01
25040	Explore/treat wrist joint	Y		A2	23.014	$952.62
25065	Biopsy forearm soft tissues	Y		P3	3.459	$143.18
25066	Biopsy forearm soft tissues	Y		A2	15.9027	$658.26
25075	Removal forearm lesion subcu	Y		A2	13.0039	$538.27
25076	Removal forearm lesion deep	Y		A2	16.6567	$689.47
25077	Remove tumor, forearm/wrist	Y		A2	16.6567	$689.47
25085	Incision of wrist capsule	Y		A2	16.6265	$688.22
25100	Biopsy of wrist joint	Y		A2	15.8725	$657.01
25101	Explore/treat wrist joint	Y		A2	20.5759	$851.70
25105	Remove wrist joint lining	Y		A2	21.9892	$910.20
25107	Remove wrist joint cartilage	Y		A2	20.5759	$851.70
25109	Excise tendon forearm/wrist	Y		G2	21.2387	$879.13
25110	Remove wrist tendon lesion	Y		A2	16.6265	$688.22
25111	Remove wrist tendon lesion	Y		A2	16.6265	$688.22
25112	Reremove wrist tendon lesion	Y		A2	18.0398	$746.72
25115	Remove wrist/forearm lesion	Y		A2	18.0398	$746.72
25116	Remove wrist/forearm lesion	Y		A2	18.0398	$746.72
25118	Excise wrist tendon sheath	Y		A2	19.822	$820.49
25119	Partial removal of ulna	Y		A2	20.5759	$851.70
25120	Removal of forearm lesion	Y		A2	20.5759	$851.70
25125	Remove/graft forearm lesion	Y		A2	20.5759	$851.70

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ADDENDUM AA.--FINAL ASC COVERED SURGICAL PROCEDURES FOR CY 2009 (INCLUDING SURGICAL PROCEDURES FOR WHICH PAYMENT IS PACKAGED)						
HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
25126	Remove/graft forearm lesion	Y		A2	20.5759	$851.70
25130	Removal of wrist lesion	Y		A2	20.5759	$851.70
25135	Remove & graft wrist lesion	Y		A2	20.5759	$851.70
25136	Remove & graft wrist lesion	Y		A2	20.5759	$851.70
25145	Remove forearm bone lesion	Y		A2	19.822	$820.49
25150	Partial removal of ulna	Y		A2	19.822	$820.49
25151	Partial removal of radius	Y		A2	19.822	$820.49
25210	Removal of wrist bone	Y		A2	20.5759	$851.70
25215	Removal of wrist bones	Y		A2	21.9892	$910.20
25230	Partial removal of radius	Y		A2	21.9892	$910.20
25240	Partial removal of ulna	Y		A2	21.9892	$910.20
25246	Injection for wrist x-ray	N		N1		
25248	Remove forearm foreign body	Y		A2	15.8725	$657.01
25250	Removal of wrist prosthesis	Y		A2	18.491	$765.40
25251	Removal of wrist prosthesis	Y		A2	18.491	$765.40
25259	Manipulate wrist w/anesthes	Y		G2	19.3776	$802.10
25260	Repair forearm tendon/muscle	Y		A2	21.9892	$910.20
25263	Repair forearm tendon/muscle	Y		A2	19.822	$820.49
25265	Repair forearm tendon/muscle	Y		A2	20.5759	$851.70
25270	Repair forearm tendon/muscle	Y		A2	21.9892	$910.20
25272	Repair forearm tendon/muscle	Y		A2	20.5759	$851.70
25274	Repair forearm tendon/muscle	Y		A2	21.9892	$910.20
25275	Repair forearm tendon sheath	Y		A2	21.9892	$910.20
25280	Revise wrist/forearm tendon	Y		A2	21.9892	$910.20
25290	Incise wrist/forearm tendon	Y		A2	20.5759	$851.70
25295	Release wrist/forearm tendon	Y		A2	16.6265	$688.22
25300	Fusion of tendons at wrist	Y		A2	20.5759	$851.70
25301	Fusion of tendons at wrist	Y		A2	20.5759	$851.70
25310	Transplant forearm tendon	Y		A2	28.119	$1,163.93
25312	Transplant forearm tendon	Y		A2	29.5325	$1,222.44
25315	Revise palsy hand tendon(s)	Y		A2	28.119	$1,163.93
25316	Revise palsy hand tendon(s)	Y		A2	48.227	$1,996.26
25320	Repair/revise wrist joint	Y		A2	28.119	$1,163.93
25332	Revise wrist joint	Y		A2	26.8898	$1,113.05
25335	Realignment of hand	Y		A2	28.119	$1,163.93
25337	Reconstruct ulna/radioulnar	Y		A2	30.5571	$1,264.85
25350	Revision of radius	Y		A2	48.227	$1,996.26
25355	Revision of radius	Y		A2	28.119	$1,163.93

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25360	Revision of ulna	Y		A2	20.5759	$851.70
25365	Revise radius & ulna	Y		A2	20.5759	$851.70
25370	Revise radius or ulna	Y		A2	28.119	$1,163.93
25375	Revise radius & ulna	Y		A2	29.5325	$1,222.44
25390	Shorten radius or ulna	Y		A2	20.5759	$851.70
25391	Lengthen radius or ulna	Y		A2	29.5325	$1,222.44
25392	Shorten radius & ulna	Y		A2	20.5759	$851.70
25393	Lengthen radius & ulna	Y		A2	29.5325	$1,222.44
25394	Repair carpal bone, shorten	Y		G2	44.2241	$1,830.57
25400	Repair radius or ulna	Y		A2	28.119	$1,163.93
25405	Repair/graft radius or ulna	Y		A2	49.6403	$2,054.76
25415	Repair radius & ulna	Y		A2	48.227	$1,996.26
25420	Repair/graft radius & ulna	Y		A2	49.6403	$2,054.76
25425	Repair/graft radius or ulna	Y		A2	28.119	$1,163.93
25426	Repair/graft radius & ulna	Y		A2	29.5325	$1,222.44
25430	Vasc graft into carpal bone	Y		G2	44.2241	$1,830.57
25431	Repair nonunion carpal bone	Y		G2	44.2241	$1,830.57
25440	Repair/graft wrist bone	Y		A2	49.6403	$2,054.76
25441	Reconstruct wrist joint	Y	CH	H8	147.0205	$6,085.62
25442	Reconstruct wrist joint	Y	CH	H8	147.0205	$6,085.62
25443	Reconstruct wrist joint	Y		A2	34.365	$1,422.47
25444	Reconstruct wrist joint	Y		A2	34.365	$1,422.47
25445	Reconstruct wrist joint	Y		A2	34.365	$1,422.47
25446	Wrist replacement	Y	CH	H8	150.295	$6,221.16
25447	Repair wrist joint(s)	Y		A2	26.8898	$1,113.05
25449	Remove wrist joint implant	Y		A2	26.8898	$1,113.05
25450	Revision of wrist joint	Y		A2	28.119	$1,163.93
25455	Revision of wrist joint	Y		A2	28.119	$1,163.93
25490	Reinforce radius	Y		A2	28.119	$1,163.93
25491	Reinforce ulna	Y		A2	28.119	$1,163.93
25492	Reinforce radius and ulna	Y		A2	28.119	$1,163.93
25500	Treat fracture of radius	Y		P2	1.5579	$64.49
25505	Treat fracture of radius	Y		A2	4.2179	$174.59
25515	Treat fracture of radius	Y		A2	26.9062	$1,113.73
25520	Treat fracture of radius	Y		A2	4.2179	$174.59
25525	Treat fracture of radius	Y		A2	28.3198	$1,172.24
25526	Treat fracture of radius	Y		A2	29.3443	$1,214.65
25530	Treat fracture of ulna	Y		P2	1.5579	$64.49

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25535	Treat fracture of ulna	Y		A2	1.9994	$82.76
25545	Treat fracture of ulna	Y		A2	26.9062	$1,113.73
25560	Treat fracture radius & ulna	Y		P2	1.5579	$64.49
25565	Treat fracture radius & ulna	Y		A2	4.2179	$174.59
25574	Treat fracture radius & ulna	Y		A2	36.5127	$1,511.37
25575	Treat fracture radius/ulna	Y		A2	36.5127	$1,511.37
25600	Treat fracture radius/ulna	Y		P2	1.5579	$64.49
25605	Treat fracture radius/ulna	Y		A2	4.2179	$174.59
25606	Treat fx distal radial	Y		A2	18.4125	$762.15
25607	Treat fx rad extra-articul	Y		A2	38.9508	$1,612.29
25608	Treat fx rad intra-articul	Y		A2	38.9508	$1,612.29
25609	Treat fx radial 3+ frag	Y		A2	38.9508	$1,612.29
25622	Treat wrist bone fracture	Y		P2	1.5579	$64.49
25624	Treat wrist bone fracture	Y		A2	4.2179	$174.59
25628	Treat wrist bone fracture	Y		A2	26.9062	$1,113.73
25630	Treat wrist bone fracture	Y		P2	1.5579	$64.49
25635	Treat wrist bone fracture	Y		A2	4.2179	$174.59
25645	Treat wrist bone fracture	Y		A2	26.9062	$1,113.73
25650	Treat wrist bone fracture	Y		P2	1.5579	$64.49
25651	Pin ulnar styloid fracture	Y		G2	24.8106	$1,026.99
25652	Treat fracture ulnar styloid	Y		G2	41.7982	$1,730.15
25660	Treat wrist dislocation	Y		A2	1.9994	$82.76
25670	Treat wrist dislocation	Y		A2	18.4125	$762.15
25671	Pin radioulnar dislocation	Y		A2	16.3276	$675.85
25675	Treat wrist dislocation	Y		A2	1.9994	$82.76
25676	Treat wrist dislocation	Y		A2	17.6585	$730.94
25680	Treat wrist fracture	Y		A2	1.9994	$82.76
25685	Treat wrist fracture	Y		A2	18.4125	$762.15
25690	Treat wrist dislocation	Y		A2	10.9093	$451.57
25695	Treat wrist dislocation	Y		A2	17.6585	$730.94
25800	Fusion of wrist joint	Y		A2	49.6403	$2,054.76
25805	Fusion/graft of wrist joint	Y		A2	30.5571	$1,264.85
25810	Fusion/graft of wrist joint	Y		A2	50.6651	$2,097.18
25820	Fusion of hand bones	Y		A2	29.5325	$1,222.44
25825	Fuse hand bones with graft	Y		A2	50.6651	$2,097.18
25830	Fusion, radioulnar jnt/ulna	Y		A2	50.6651	$2,097.18
25907	Amputation follow-up surgery	Y		A2	16.6265	$688.22
25922	Amputate hand at wrist	Y		A2	16.6265	$688.22

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25929	Amputation follow-up surgery	Y		A2	13.7956	$571.04
25931	Amputation follow-up surgery	Y		G2	21.2387	$879.13
26010	Drainage of finger abscess	Y		P2	1.3776	$57.02
26011	Drainage of finger abscess	Y		A2	10.0631	$416.54
26020	Drain hand tendon sheath	Y		A2	13.3525	$552.70
26025	Drainage of palm bursa	Y		A2	12.0214	$497.60
26030	Drainage of palm bursa(s)	Y		A2	13.3525	$552.70
26034	Treat hand bone lesion	Y		A2	13.3525	$552.70
26035	Decompress fingers/hand	Y		G2	16.1985	$670.50
26040	Release palm contracture	Y		A2	21.0717	$872.22
26045	Release palm contracture	Y		A2	19.6582	$813.71
26055	Incise finger tendon sheath	Y		A2	13.3525	$552.70
26060	Incision of finger tendon	Y		A2	13.3525	$552.70
26070	Explore/treat hand joint	Y		A2	13.3525	$552.70
26075	Explore/treat finger joint	Y		A2	15.5198	$642.41
26080	Explore/treat finger joint	Y		A2	15.5198	$642.41
26100	Biopsy hand joint lining	Y		A2	13.3525	$552.70
26105	Biopsy finger joint lining	Y		A2	12.0214	$497.60
26110	Biopsy finger joint lining	Y		A2	12.0214	$497.60
26115	Removal hand lesion subcut	Y		A2	15.9027	$658.26
26116	Removal hand lesion, deep	Y		A2	15.9027	$658.26
26117	Remove tumor, hand/finger	Y		A2	16.6567	$689.47
26121	Release palm contracture	Y		A2	21.0717	$872.22
26123	Release palm contracture	Y		A2	21.0717	$872.22
26125	Release palm contracture	Y		A2	15.5198	$642.41
26130	Remove wrist joint lining	Y		A2	14.1062	$583.90
26135	Revise finger joint, each	Y		A2	21.0717	$872.22
26140	Revise finger joint, each	Y		A2	13.3525	$552.70
26145	Tendon excision, palm/finger	Y		A2	14.1062	$583.90
26160	Remove tendon sheath lesion	Y		A2	14.1062	$583.90
26170	Removal of palm tendon, each	Y		A2	14.1062	$583.90
26180	Removal of finger tendon	Y		A2	14.1062	$583.90
26185	Remove finger bone	Y		A2	15.5198	$642.41
26200	Remove hand bone lesion	Y		A2	13.3525	$552.70
26205	Remove/graft bone lesion	Y		A2	19.6582	$813.71
26210	Removal of finger lesion	Y		A2	13.3525	$552.70
26215	Remove/graft finger lesion	Y		A2	14.1062	$583.90
26230	Partial removal of hand bone	Y		A2	19.7947	$819.36

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26235	Partial removal, finger bone	Y		A2	14.1062	$583.90
26236	Partial removal, finger bone	Y		A2	14.1062	$583.90
26250	Extensive hand surgery	Y		A2	14.1062	$583.90
26255	Extensive hand surgery	Y		A2	19.6582	$813.71
26260	Extensive finger surgery	Y		A2	14.1062	$583.90
26261	Extensive finger surgery	Y		A2	14.1062	$583.90
26262	Partial removal of finger	Y		A2	13.3525	$552.70
26320	Removal of implant from hand	Y		A2	13.0039	$538.27
26340	Manipulate finger w/anesth	Y		G2	5.9948	$248.14
26350	Repair finger/hand tendon	Y		A2	17.5733	$727.41
26352	Repair/graft hand tendon	Y		A2	21.0717	$872.22
26356	Repair finger/hand tendon	Y		A2	21.0717	$872.22
26357	Repair finger/hand tendon	Y		A2	21.0717	$872.22
26358	Repair/graft hand tendon	Y		A2	21.0717	$872.22
26370	Repair finger/hand tendon	Y		A2	21.0717	$872.22
26372	Repair/graft hand tendon	Y		A2	21.0717	$872.22
26373	Repair finger/hand tendon	Y		A2	19.6582	$813.71
26390	Revise hand/finger tendon	Y		A2	21.0717	$872.22
26392	Repair/graft hand tendon	Y		A2	19.6582	$813.71
26410	Repair hand tendon	Y		A2	14.1062	$583.90
26412	Repair/graft hand tendon	Y		A2	19.6582	$813.71
26415	Excision, hand/finger tendon	Y		A2	21.0717	$872.22
26416	Graft hand or finger tendon	Y		A2	19.6582	$813.71
26418	Repair finger tendon	Y		A2	15.5198	$642.41
26420	Repair/graft finger tendon	Y		A2	21.0717	$872.22
26426	Repair finger/hand tendon	Y		A2	19.6582	$813.71
26428	Repair/graft finger tendon	Y		A2	19.6582	$813.71
26432	Repair finger tendon	Y		A2	14.1062	$583.90
26433	Repair finger tendon	Y		A2	14.1062	$583.90
26434	Repair/graft finger tendon	Y		A2	19.6582	$813.71
26437	Realignment of tendons	Y		A2	14.1062	$583.90
26440	Release palm/finger tendon	Y		A2	14.1062	$583.90
26442	Release palm & finger tendon	Y		A2	19.6582	$813.71
26445	Release hand/finger tendon	Y		A2	14.1062	$583.90
26449	Release forearm/hand tendon	Y		A2	19.6582	$813.71
26450	Incision of palm tendon	Y		A2	14.1062	$583.90
26455	Incision of finger tendon	Y		A2	14.1062	$583.90
26460	Incise hand/finger tendon	Y		A2	14.1062	$583.90

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26471	Fusion of finger tendons	Y		A2	13.3525	$552.70
26474	Fusion of finger tendons	Y		A2	13.3525	$552.70
26476	Tendon lengthening	Y		A2	12.0214	$497.60
26477	Tendon shortening	Y		A2	12.0214	$497.60
26478	Lengthening of hand tendon	Y		A2	12.0214	$497.60
26479	Shortening of hand tendon	Y		A2	12.0214	$497.60
26480	Transplant hand tendon	Y		A2	19.6582	$813.71
26483	Transplant/graft hand tendon	Y		A2	19.6582	$813.71
26485	Transplant palm tendon	Y		A2	18.9044	$782.51
26489	Transplant/graft palm tendon	Y		A2	19.6582	$813.71
26490	Revise thumb tendon	Y		A2	19.6582	$813.71
26492	Tendon transfer with graft	Y		A2	19.6582	$813.71
26494	Hand tendon/muscle transfer	Y		A2	19.6582	$813.71
26496	Revise thumb tendon	Y		A2	19.6582	$813.71
26497	Finger tendon transfer	Y		A2	19.6582	$813.71
26498	Finger tendon transfer	Y		A2	21.0717	$872.22
26499	Revision of finger	Y		A2	19.6582	$813.71
26500	Hand tendon reconstruction	Y		A2	15.5198	$642.41
26502	Hand tendon reconstruction	Y		A2	21.0717	$872.22
26508	Release thumb contracture	Y		A2	14.1062	$583.90
26510	Thumb tendon transfer	Y		A2	19.6582	$813.71
26516	Fusion of knuckle joint	Y		A2	17.5733	$727.41
26517	Fusion of knuckle joints	Y		A2	19.6582	$813.71
26518	Fusion of knuckle joints	Y		A2	19.6582	$813.71
26520	Release knuckle contracture	Y		A2	14.1062	$583.90
26525	Release finger contracture	Y		A2	14.1062	$583.90
26530	Revise knuckle joint	Y		A2	24.4517	$1,012.13
26531	Revise knuckle with implant	Y		A2	37.6395	$1,558.01
26535	Revise finger joint	Y		A2	26.8898	$1,113.05
26536	Revise/implant finger joint	Y		A2	34.365	$1,422.47
26540	Repair hand joint	Y		A2	15.5198	$642.41
26541	Repair hand joint with graft	Y		A2	25.3707	$1,050.17
26542	Repair hand joint with graft	Y		A2	15.5198	$642.41
26545	Reconstruct finger joint	Y		A2	21.0717	$872.22
26546	Repair nonunion hand	Y		A2	21.0717	$872.22
26548	Reconstruct finger joint	Y		A2	21.0717	$872.22
26550	Construct thumb replacement	Y		A2	18.9044	$782.51
26555	Positional change of finger	Y		A2	19.6582	$813.71

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26560	Repair of web finger	Y		A2	13.3525	$552.70
26561	Repair of web finger	Y		A2	19.6582	$813.71
26562	Repair of web finger	Y		A2	21.0717	$872.22
26565	Correct metacarpal flaw	Y		A2	22.0962	$914.63
26567	Correct finger deformity	Y		A2	22.0962	$914.63
26568	Lengthen metacarpal/finger	Y		A2	19.6582	$813.71
26580	Repair hand deformity	Y		A2	16.5443	$684.82
26587	Reconstruct extra finger	Y		A2	16.5443	$684.82
26590	Repair finger deformity	Y		A2	16.5443	$684.82
26591	Repair muscles of hand	Y		A2	19.6582	$813.71
26593	Release muscles of hand	Y		A2	14.1062	$583.90
26596	Excision constricting tissue	Y		A2	13.3525	$552.70
26600	Treat metacarpal fracture	Y		P2	1.5579	$64.49
26605	Treat metacarpal fracture	Y		A2	1.9994	$82.76
26607	Treat metacarpal fracture	Y		A2	10.9093	$451.57
26608	Treat metacarpal fracture	Y		A2	19.8258	$820.65
26615	Treat metacarpal fracture	Y		A2	28.3198	$1,172.24
26641	Treat thumb dislocation	Y		P2	1.5579	$64.49
26645	Treat thumb fracture	Y		A2	4.2179	$174.59
26650	Treat thumb fracture	Y		A2	17.6585	$730.94
26665	Treat thumb fracture	Y		A2	28.3198	$1,172.24
26670	Treat hand dislocation	Y		P2	1.5579	$64.49
26675	Treat hand dislocation	Y		A2	4.2179	$174.59
26676	Pin hand dislocation	Y		A2	17.6585	$730.94
26685	Treat hand dislocation	Y		A2	18.4125	$762.15
26686	Treat hand dislocation	Y		A2	36.5127	$1,511.37
26700	Treat knuckle dislocation	Y		P2	1.5579	$64.49
26705	Treat knuckle dislocation	Y		A2	1.9994	$82.76
26706	Pin knuckle dislocation	Y		A2	10.9093	$451.57
26715	Treat knuckle dislocation	Y		A2	19.8258	$820.65
26720	Treat finger fracture, each	Y		P2	1.5579	$64.49
26725	Treat finger fracture, each	Y		P2	1.5579	$64.49
26727	Treat finger fracture, each	Y		A2	24.1251	$998.61
26735	Treat finger fracture, each	Y		A2	19.8258	$820.65
26740	Treat finger fracture, each	Y		P2	1.5579	$64.49
26742	Treat finger fracture, each	Y		A2	1.9994	$82.76
26746	Treat finger fracture, each	Y		A2	20.8506	$863.07
26750	Treat finger fracture, each	Y		P2	1.5579	$64.49

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ADDENDUM AA.--FINAL ASC COVERED SURGICAL PROCEDURES FOR CY 2009 (INCLUDING SURGICAL PROCEDURES FOR WHICH PAYMENT IS PACKAGED)						
HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
26755	Treat finger fracture, each	Y		G2	1.5579	$64.49
26756	Pin finger fracture, each	Y		A2	17.6585	$730.94
26765	Treat finger fracture, each	Y		A2	19.8258	$820.65
26770	Treat finger dislocation	Y		G2	1.5579	$64.49
26775	Treat finger dislocation	Y		P3	4.165	$172.40
26776	Pin finger dislocation	Y		A2	17.6585	$730.94
26785	Treat finger dislocation	Y		A2	17.6585	$730.94
26820	Thumb fusion with graft	Y		A2	22.0962	$914.63
26841	Fusion of thumb	Y		A2	21.0717	$872.22
26842	Thumb fusion with graft	Y		A2	21.0717	$872.22
26843	Fusion of hand joint	Y		A2	19.6582	$813.71
26844	Fusion/graft of hand joint	Y		A2	19.6582	$813.71
26850	Fusion of knuckle	Y		A2	21.0717	$872.22
26852	Fusion of knuckle with graft	Y		A2	21.0717	$872.22
26860	Fusion of finger joint	Y		A2	19.6582	$813.71
26861	Fusion of finger jnt, add-on	Y		A2	18.9044	$782.51
26862	Fusion/graft of finger joint	Y		A2	21.0717	$872.22
26863	Fuse/graft added joint	Y		A2	19.6582	$813.71
26910	Amputate metacarpal bone	Y		A2	19.6582	$813.71
26951	Amputation of finger/thumb	Y		A2	13.3525	$552.70
26952	Amputation of finger/thumb	Y		A2	15.5198	$642.41
26990	Drainage of pelvis lesion	Y		A2	14.5416	$601.92
26991	Drainage of pelvis bursa	Y		A2	14.5416	$601.92
27000	Incision of hip tendon	Y		A2	15.8725	$657.01
27001	Incision of hip tendon	Y		A2	20.5759	$851.70
27003	Incision of hip tendon	Y		A2	20.5759	$851.70
27033	Exploration of hip joint	Y		A2	28.119	$1,163.93
27035	Denervation of hip joint	Y		A2	29.5325	$1,222.44
27040	Biopsy of soft tissues	Y		A2	7.9477	$328.98
27041	Biopsy of soft tissues	Y		A2	8.9547	$370.66
27047	Remove hip/pelvis lesion	Y		A2	15.9027	$658.26
27048	Remove hip/pelvis lesion	Y		A2	16.6567	$689.47
27049	Remove tumor, hip/pelvis	Y		A2	16.6567	$689.47
27050	Biopsy of sacroiliac joint	Y		A2	16.6265	$688.22
27052	Biopsy of hip joint	Y		A2	16.6265	$688.22
27060	Removal of ischial bursa	Y		A2	19.0646	$789.14
27062	Remove femur lesion/bursa	Y		A2	19.0646	$789.14
27065	Removal of hip bone lesion	Y		A2	19.0646	$789.14

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HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
27066	Removal of hip bone lesion	Y		A2	23.014	$952.62
27067	Remove/graft hip bone lesion	Y		A2	23.014	$952.62
27080	Removal of tail bone	Y		A2	19.822	$820.49
27086	Remove hip foreign body	Y		A2	7.9477	$328.98
27087	Remove hip foreign body	Y		A2	16.6265	$688.22
27093	Injection for hip x-ray	N		N1		
27095	Injection for hip x-ray	N		N1		
27097	Revision of hip tendon	Y		A2	20.5759	$851.70
27098	Transfer tendon to pelvis	Y		A2	20.5759	$851.70
27100	Transfer of abdominal muscle	Y		A2	29.5325	$1,222.44
27105	Transfer of spinal muscle	Y		A2	29.5325	$1,222.44
27110	Transfer of iliopsoas muscle	Y		A2	29.5325	$1,222.44
27111	Transfer of iliopsoas muscle	Y		A2	29.5325	$1,222.44
27193	Treat pelvic ring fracture	Y		A2	1.9994	$82.76
27194	Treat pelvic ring fracture	Y		A2	12.843	$531.61
27200	Treat tail bone fracture	Y		P2	1.5579	$64.49
27202	Treat tail bone fracture	Y		A2	26.1525	$1,082.53
27220	Treat hip socket fracture	Y		G2	1.5579	$64.49
27230	Treat thigh fracture	Y		A2	1.9994	$82.76
27238	Treat thigh fracture	Y		A2	4.2179	$174.59
27246	Treat thigh fracture	Y		A2	4.2179	$174.59
27250	Treat hip dislocation	Y		A2	1.9994	$82.76
27252	Treat hip dislocation	Y		A2	12.843	$531.61
27256	Treat hip dislocation	Y		G2	1.5579	$64.49
27257	Treat hip dislocation	Y		A2	13.597	$562.82
27265	Treat hip dislocation	Y		A2	1.9994	$82.76
27266	Treat hip dislocation	Y		A2	12.843	$531.61
27267	Cltx thigh fx	Y		G2	1.5579	$64.49
27275	Manipulation of hip joint	Y		A2	12.843	$531.61
27301	Drain thigh/knee lesion	Y		A2	15.4594	$639.91
27305	Incise thigh tendon & fascia	Y		A2	15.8725	$657.01
27306	Incision of thigh tendon	Y		A2	16.6265	$688.22
27307	Incision of thigh tendons	Y		A2	16.6265	$688.22
27310	Exploration of knee joint	Y		A2	21.9892	$910.20
27323	Biopsy, thigh soft tissues	Y		A2	7.9477	$328.98
27324	Biopsy, thigh soft tissues	Y		A2	14.5718	$603.17
27325	Neurectomy, hamstring	Y		A2	14.2783	$591.02
27326	Neurectomy, popliteal	Y		A2	14.2783	$591.02

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HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
27327	Removal of thigh lesion	Y		A2	15.9027	$658.26
27328	Removal of thigh lesion	Y		A2	16.6567	$689.47
27329	Remove tumor, thigh/knee	Y		A2	18.07	$747.97
27330	Biopsy, knee joint lining	Y		A2	21.9892	$910.20
27331	Explore/treat knee joint	Y		A2	21.9892	$910.20
27332	Removal of knee cartilage	Y		A2	21.9892	$910.20
27333	Removal of knee cartilage	Y		A2	21.9892	$910.20
27334	Remove knee joint lining	Y		A2	21.9892	$910.20
27335	Remove knee joint lining	Y		A2	21.9892	$910.20
27340	Removal of kneecap bursa	Y		A2	16.6265	$688.22
27345	Removal of knee cyst	Y		A2	18.0398	$746.72
27347	Remove knee cyst	Y		A2	18.0398	$746.72
27350	Removal of kneecap	Y		A2	21.9892	$910.20
27355	Remove femur lesion	Y		A2	20.5759	$851.70
27356	Remove femur lesion/graft	Y		A2	21.9892	$910.20
27357	Remove femur lesion/graft	Y		A2	23.014	$952.62
27358	Remove femur lesion/fixation	Y		A2	23.014	$952.62
27360	Partial removal, leg bone(s)	Y		A2	23.014	$952.62
27370	Injection for knee x-ray	N		N1		
27372	Removal of foreign body	Y		A2	22.3692	$925.93
27380	Repair of kneecap tendon	Y		A2	14.5416	$601.92
27381	Repair/graft kneecap tendon	Y		A2	16.6265	$688.22
27385	Repair of thigh muscle	Y		A2	16.6265	$688.22
27386	Repair/graft of thigh muscle	Y		A2	16.6265	$688.22
27390	Incision of thigh tendon	Y		A2	14.5416	$601.92
27391	Incision of thigh tendons	Y		A2	15.8725	$657.01
27392	Incision of thigh tendons	Y		A2	16.6265	$688.22
27393	Lengthening of thigh tendon	Y		A2	19.822	$820.49
27394	Lengthening of thigh tendons	Y		A2	20.5759	$851.70
27395	Lengthening of thigh tendons	Y		A2	28.119	$1,163.93
27396	Transplant of thigh tendon	Y		A2	20.5759	$851.70
27397	Transplants of thigh tendons	Y		A2	28.119	$1,163.93
27400	Revise thigh muscles/tendons	Y		A2	28.119	$1,163.93
27403	Repair of knee cartilage	Y		A2	21.9892	$910.20
27405	Repair of knee ligament	Y		A2	29.5325	$1,222.44
27407	Repair of knee ligament	Y		A2	49.6403	$2,054.76
27409	Repair of knee ligaments	Y		A2	29.5325	$1,222.44
27416	Osteochondral knee autograft	Y		G2	44.2241	$1,830.57

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27418	Repair degenerated kneecap	Y		A2	28.119	$1,163.93
27420	Revision of unstable kneecap	Y		A2	28.119	$1,163.93
27422	Revision of unstable kneecap	Y		A2	33.8316	$1,400.39
27424	Revision/removal of kneecap	Y		A2	28.119	$1,163.93
27425	Lat retinacular release open	Y		A2	26.2885	$1,088.16
27427	Reconstruction, knee	Y		A2	28.119	$1,163.93
27428	Reconstruction, knee	Y		A2	49.6403	$2,054.76
27429	Reconstruction, knee	Y		A2	49.6403	$2,054.76
27430	Revision of thigh muscles	Y		A2	29.5325	$1,222.44
27435	Incision of knee joint	Y		A2	29.5325	$1,222.44
27437	Revise kneecap	Y		A2	25.865	$1,070.63
27438	Revise kneecap with implant	Y		A2	34.365	$1,422.47
27440	Revision of knee joint	Y		G2	36.889	$1,526.95
27441	Revision of knee joint	Y		A2	26.8898	$1,113.05
27442	Revision of knee joint	Y		A2	26.8898	$1,113.05
27443	Revision of knee joint	Y		A2	26.8898	$1,113.05
27446	Revision of knee joint	Y	CH	J8	263.841	$10,921.17
27496	Decompression of thigh/knee	Y		A2	19.0646	$789.14
27497	Decompression of thigh/knee	Y		A2	16.6265	$688.22
27498	Decompression of thigh/knee	Y		A2	16.6265	$688.22
27499	Decompression of thigh/knee	Y		A2	16.6265	$688.22
27500	Treatment of thigh fracture	Y		A2	4.2179	$174.59
27501	Treatment of thigh fracture	Y		A2	1.9994	$82.76
27502	Treatment of thigh fracture	Y		A2	10.9093	$451.57
27503	Treatment of thigh fracture	Y		A2	1.9994	$82.76
27508	Treatment of thigh fracture	Y		A2	1.9994	$82.76
27509	Treatment of thigh fracture	Y		A2	18.4125	$762.15
27510	Treatment of thigh fracture	Y		A2	4.2179	$174.59
27516	Treat thigh fx growth plate	Y		A2	1.9994	$82.76
27517	Treat thigh fx growth plate	Y		A2	1.9994	$82.76
27520	Treat kneecap fracture	Y		A2	1.9994	$82.76
27530	Treat knee fracture	Y		A2	1.9994	$82.76
27532	Treat knee fracture	Y		A2	10.9093	$451.57
27538	Treat knee fracture(s)	Y		A2	1.9994	$82.76
27550	Treat knee dislocation	Y		A2	1.9994	$82.76
27552	Treat knee dislocation	Y		A2	11.5121	$476.52
27560	Treat kneecap dislocation	Y		A2	1.9994	$82.76
27562	Treat kneecap dislocation	Y		A2	11.5121	$476.52

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27566	Treat kneecap dislocation	Y		A2	26.1525	$1,082.53
27570	Fixation of knee joint	Y		A2	11.5121	$476.52
27594	Amputation follow-up surgery	Y		A2	16.6265	$688.22
27600	Decompression of lower leg	Y		A2	16.6265	$688.22
27601	Decompression of lower leg	Y		A2	16.6265	$688.22
27602	Decompression of lower leg	Y		A2	16.6265	$688.22
27603	Drain lower leg lesion	Y		A2	14.7056	$608.71
27604	Drain lower leg bursa	Y		A2	15.8725	$657.01
27605	Incision of achilles tendon	Y		A2	14.4636	$598.69
27606	Incision of achilles tendon	Y		A2	14.5416	$601.92
27607	Treat lower leg bone lesion	Y		A2	15.8725	$657.01
27610	Explore/treat ankle joint	Y		A2	19.822	$820.49
27612	Exploration of ankle joint	Y		A2	20.5759	$851.70
27613	Biopsy lower leg soft tissue	Y		P3	3.2675	$135.25
27614	Biopsy lower leg soft tissue	Y		A2	15.9027	$658.26
27615	Remove tumor, lower leg	Y		A2	20.5759	$851.70
27618	Remove lower leg lesion	Y		A2	13.0039	$538.27
27619	Remove lower leg lesion	Y		A2	16.6567	$689.47
27620	Explore/treat ankle joint	Y		A2	21.9892	$910.20
27625	Remove ankle joint lining	Y		A2	21.9892	$910.20
27626	Remove ankle joint lining	Y		A2	21.9892	$910.20
27630	Removal of tendon lesion	Y		A2	16.6265	$688.22
27635	Remove lower leg bone lesion	Y		A2	20.5759	$851.70
27637	Remove/graft leg bone lesion	Y		A2	20.5759	$851.70
27638	Remove/graft leg bone lesion	Y		A2	20.5759	$851.70
27640	Partial removal of tibia	Y		A2	27.3653	$1,132.73
27641	Partial removal of fibula	Y		A2	19.822	$820.49
27647	Extensive ankle/heel surgery	Y		A2	28.119	$1,163.93
27648	Injection for ankle x-ray	N		N1		
27650	Repair achilles tendon	Y		A2	28.119	$1,163.93
27652	Repair/graft achilles tendon	Y		A2	48.227	$1,996.26
27654	Repair of achilles tendon	Y		A2	28.119	$1,163.93
27656	Repair leg fascia defect	Y		A2	15.8725	$657.01
27658	Repair of leg tendon, each	Y		A2	14.5416	$601.92
27659	Repair of leg tendon, each	Y		A2	15.8725	$657.01
27664	Repair of leg tendon, each	Y		A2	15.8725	$657.01
27665	Repair of leg tendon, each	Y		A2	19.822	$820.49
27675	Repair lower leg tendons	Y		A2	15.8725	$657.01

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27676	Repair lower leg tendons	Y		A2	20.5759	$851.70
27680	Release of lower leg tendon	Y		A2	20.5759	$851.70
27681	Release of lower leg tendons	Y		A2	19.822	$820.49
27685	Revision of lower leg tendon	Y		A2	20.5759	$851.70
27686	Revise lower leg tendons	Y		A2	20.5759	$851.70
27687	Revision of calf tendon	Y		A2	20.5759	$851.70
27690	Revise lower leg tendon	Y		A2	29.5325	$1,222.44
27691	Revise lower leg tendon	Y		A2	29.5325	$1,222.44
27692	Revise additional leg tendon	Y		A2	28.119	$1,163.93
27695	Repair of ankle ligament	Y		A2	19.822	$820.49
27696	Repair of ankle ligaments	Y		A2	19.822	$820.49
27698	Repair of ankle ligament	Y		A2	19.822	$820.49
27700	Revision of ankle joint	Y		A2	26.8898	$1,113.05
27704	Removal of ankle implant	Y		A2	15.8725	$657.01
27705	Incision of tibia	Y		A2	27.3653	$1,132.73
27707	Incision of fibula	Y		A2	15.8725	$657.01
27709	Incision of tibia & fibula	Y		A2	19.822	$820.49
27726	Repair fibula nonunion	Y		G2	24.8106	$1,026.99
27730	Repair of tibia epiphysis	Y		A2	19.822	$820.49
27732	Repair of fibula epiphysis	Y		A2	19.822	$820.49
27734	Repair lower leg epiphyses	Y		A2	19.822	$820.49
27740	Repair of leg epiphyses	Y		A2	19.822	$820.49
27742	Repair of leg epiphyses	Y		A2	27.3653	$1,132.73
27745	Reinforce tibia	Y		A2	48.227	$1,996.26
27750	Treatment of tibia fracture	Y		A2	1.9994	$82.76
27752	Treatment of tibia fracture	Y		A2	10.9093	$451.57
27756	Treatment of tibia fracture	Y		A2	18.4125	$762.15
27758	Treatment of tibia fracture	Y		A2	28.3198	$1,172.24
27759	Treatment of tibia fracture	Y		A2	37.926	$1,569.87
27760	Cltx medial ankle fx	Y		A2	1.9994	$82.76
27762	Cltx med ankle fx w/mnpj	Y		A2	10.9093	$451.57
27766	Optx medial ankle fx	Y		A2	26.9062	$1,113.73
27767	Cltx post ankle fx	Y		G2	1.5579	$64.49
27768	Cltx post ankle fx w/mnpj	Y		G2	1.5579	$64.49
27769	Optx post ankle fx	Y		G2	41.7982	$1,730.15
27780	Treatment of fibula fracture	Y		A2	1.9994	$82.76
27781	Treatment of fibula fracture	Y		A2	10.9093	$451.57
27784	Treatment of fibula fracture	Y		A2	26.9062	$1,113.73

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27786	Treatment of ankle fracture	Y		A2	1.9994	$82.76
27788	Treatment of ankle fracture	Y		A2	1.9994	$82.76
27792	Treatment of ankle fracture	Y		A2	26.9062	$1,113.73
27808	Treatment of ankle fracture	Y		A2	1.9994	$82.76
27810	Treatment of ankle fracture	Y		A2	4.2179	$174.59
27814	Treatment of ankle fracture	Y		A2	26.9062	$1,113.73
27816	Treatment of ankle fracture	Y		A2	1.9994	$82.76
27818	Treatment of ankle fracture	Y		A2	4.2179	$174.59
27822	Treatment of ankle fracture	Y		A2	26.9062	$1,113.73
27823	Treatment of ankle fracture	Y		A2	36.5127	$1,511.37
27824	Treat lower leg fracture	Y		A2	1.9994	$82.76
27825	Treat lower leg fracture	Y		A2	10.9093	$451.57
27826	Treat lower leg fracture	Y		A2	26.9062	$1,113.73
27827	Treat lower leg fracture	Y		A2	36.5127	$1,511.37
27828	Treat lower leg fracture	Y		A2	37.926	$1,569.87
27829	Treat lower leg joint	Y		A2	26.1525	$1,082.53
27830	Treat lower leg dislocation	Y		A2	1.9994	$82.76
27831	Treat lower leg dislocation	Y		A2	10.9093	$451.57
27832	Treat lower leg dislocation	Y		A2	26.1525	$1,082.53
27840	Treat ankle dislocation	Y		A2	4.2179	$174.59
27842	Treat ankle dislocation	Y		A2	11.5121	$476.52
27846	Treat ankle dislocation	Y		A2	26.9062	$1,113.73
27848	Treat ankle dislocation	Y		A2	26.9062	$1,113.73
27860	Fixation of ankle joint	Y		A2	11.5121	$476.52
27870	Fusion of ankle joint, open	Y		A2	49.6403	$2,054.76
27871	Fusion of tibiofibular joint	Y		A2	49.6403	$2,054.76
27884	Amputation follow-up surgery	Y		A2	16.6265	$688.22
27889	Amputation of foot at ankle	Y		A2	20.5759	$851.70
27892	Decompression of leg	Y		A2	16.6265	$688.22
27893	Decompression of leg	Y		A2	16.6265	$688.22
27894	Decompression of leg	Y		A2	16.6265	$688.22
28001	Drainage of bursa of foot	Y		P3	3.1889	$132.00
28002	Treatment of foot infection	Y		A2	16.6265	$688.22
28003	Treatment of foot infection	Y		A2	16.6265	$688.22
28005	Treat foot bone lesion	Y		A2	16.5485	$684.99
28008	Incision of foot fascia	Y		A2	16.5485	$684.99
28010	Incision of toe tendon	Y		P3	2.3439	$97.02
28011	Incision of toe tendons	Y		A2	16.5485	$684.99

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HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
28020	Exploration of foot joint	Y		A2	15.7945	$653.78
28022	Exploration of foot joint	Y		A2	15.7945	$653.78
28024	Exploration of toe joint	Y		A2	15.7945	$653.78
28035	Decompression of tibia nerve	Y		A2	16.4455	$680.73
28043	Excision of foot lesion	Y		A2	15.9027	$658.26
28045	Excision of foot lesion	Y		A2	16.5485	$684.99
28046	Resection of tumor, foot	Y		A2	16.5485	$684.99
28050	Biopsy of foot joint lining	Y		A2	15.7945	$653.78
28052	Biopsy of foot joint lining	Y		A2	15.7945	$653.78
28054	Biopsy of toe joint lining	Y		A2	15.7945	$653.78
28055	Neurectomy, foot	Y		A2	16.4455	$680.73
28060	Partial removal, foot fascia	Y		A2	15.7945	$653.78
28062	Removal of foot fascia	Y		A2	16.5485	$684.99
28070	Removal of foot joint lining	Y		A2	16.5485	$684.99
28072	Removal of foot joint lining	Y		A2	16.5485	$684.99
28080	Removal of foot lesion	Y		A2	16.5485	$684.99
28086	Excise foot tendon sheath	Y		A2	15.7945	$653.78
28088	Excise foot tendon sheath	Y		A2	15.7945	$653.78
28090	Removal of foot lesion	Y		A2	16.5485	$684.99
28092	Removal of toe lesions	Y		A2	16.5485	$684.99
28100	Removal of ankle/heel lesion	Y		A2	15.7945	$653.78
28102	Remove/graft foot lesion	Y		A2	29.0641	$1,203.05
28103	Remove/graft foot lesion	Y		A2	29.0641	$1,203.05
28104	Removal of foot lesion	Y		A2	15.7945	$653.78
28106	Remove/graft foot lesion	Y		A2	29.0641	$1,203.05
28107	Remove/graft foot lesion	Y		A2	29.0641	$1,203.05
28108	Removal of toe lesions	Y		A2	15.7945	$653.78
28110	Part removal of metatarsal	Y		A2	16.5485	$684.99
28111	Part removal of metatarsal	Y		A2	16.5485	$684.99
28112	Part removal of metatarsal	Y		A2	16.5485	$684.99
28113	Part removal of metatarsal	Y		A2	16.5485	$684.99
28114	Removal of metatarsal heads	Y		A2	16.5485	$684.99
28116	Revision of foot	Y		A2	16.5485	$684.99
28118	Removal of heel bone	Y		A2	17.9617	$743.49
28119	Removal of heel spur	Y		A2	17.9617	$743.49
28120	Part removal of ankle/heel	Y		A2	22.261	$921.45
28122	Partial removal of foot bone	Y		A2	16.5485	$684.99
28124	Partial removal of toe	Y		P3	5.3934	$223.25

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28126	Partial removal of toe	Y		A2	16.5485	$684.99
28130	Removal of ankle bone	Y		A2	16.5485	$684.99
28140	Removal of metatarsal	Y		A2	16.5485	$684.99
28150	Removal of toe	Y		A2	16.5485	$684.99
28153	Partial removal of toe	Y		A2	16.5485	$684.99
28160	Partial removal of toe	Y		A2	16.5485	$684.99
28171	Extensive foot surgery	Y		A2	16.5485	$684.99
28173	Extensive foot surgery	Y		A2	16.5485	$684.99
28175	Extensive foot surgery	Y		A2	16.5485	$684.99
28190	Removal of foot foreign body	Y		P3	3.2936	$136.33
28192	Removal of foot foreign body	Y		A2	13.0039	$538.27
28193	Removal of foot foreign body	Y		A2	8.9547	$370.66
28200	Repair of foot tendon	Y		A2	16.5485	$684.99
28202	Repair/graft of foot tendon	Y		A2	16.5485	$684.99
28208	Repair of foot tendon	Y		A2	16.5485	$684.99
28210	Repair/graft of foot tendon	Y		A2	29.0641	$1,203.05
28220	Release of foot tendon	Y		P3	5.0798	$210.27
28222	Release of foot tendons	Y		A2	14.4636	$598.69
28225	Release of foot tendon	Y		A2	14.4636	$598.69
28226	Release of foot tendons	Y		A2	14.4636	$598.69
28230	Incision of foot tendon(s)	Y		P3	4.9839	$206.30
28232	Incision of toe tendon	Y		P3	4.766	$197.28
28234	Incision of foot tendon	Y		A2	15.7945	$653.78
28238	Revision of foot tendon	Y		A2	29.0641	$1,203.05
28240	Release of big toe	Y		A2	15.7945	$653.78
28250	Revision of foot fascia	Y		A2	16.5485	$684.99
28260	Release of midfoot joint	Y		A2	16.5485	$684.99
28261	Revision of foot tendon	Y		A2	16.5485	$684.99
28262	Revision of foot and ankle	Y		A2	17.9617	$743.49
28264	Release of midfoot joint	Y		A2	26.9792	$1,116.75
28270	Release of foot contracture	Y		A2	16.5485	$684.99
28272	Release of toe joint, each	Y		P3	4.6005	$190.43
28280	Fusion of toes	Y		A2	15.7945	$653.78
28285	Repair of hammertoe	Y		A2	16.5485	$684.99
28286	Repair of hammertoe	Y		A2	17.9617	$743.49
28288	Partial removal of foot bone	Y		A2	16.5485	$684.99
28289	Repair hallux rigidus	Y		A2	16.5485	$684.99
28290	Correction of bunion	Y		A2	20.3981	$844.34

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28292	Correction of bunion	Y		A2	20.3981	$844.34
28293	Correction of bunion	Y		A2	21.1519	$875.54
28294	Correction of bunion	Y		A2	21.1519	$875.54
28296	Correction of bunion	Y		A2	21.1519	$875.54
28297	Correction of bunion	Y		A2	21.1519	$875.54
28298	Correction of bunion	Y		A2	21.1519	$875.54
28299	Correction of bunion	Y		A2	23.59	$976.46
28300	Incision of heel bone	Y		A2	28.3103	$1,171.85
28302	Incision of ankle bone	Y		A2	15.7945	$653.78
28304	Incision of midfoot bones	Y		A2	28.3103	$1,171.85
28305	Incise/graft midfoot bones	Y		A2	29.0641	$1,203.05
28306	Incision of metatarsal	Y		A2	17.9617	$743.49
28307	Incision of metatarsal	Y		A2	17.9617	$743.49
28308	Incision of metatarsal	Y		A2	15.7945	$653.78
28309	Incision of metatarsals	Y		A2	30.4776	$1,261.56
28310	Revision of big toe	Y		A2	16.5485	$684.99
28312	Revision of toe	Y		A2	16.5485	$684.99
28313	Repair deformity of toe	Y		A2	15.7945	$653.78
28315	Removal of sesamoid bone	Y		A2	17.9617	$743.49
28320	Repair of foot bones	Y		A2	30.4776	$1,261.56
28322	Repair of metatarsals	Y		A2	30.4776	$1,261.56
28340	Resect enlarged toe tissue	Y		A2	17.9617	$743.49
28341	Resect enlarged toe	Y		A2	17.9617	$743.49
28344	Repair extra toe(s)	Y		A2	17.9617	$743.49
28345	Repair webbed toe(s)	Y		A2	17.9617	$743.49
28400	Treatment of heel fracture	Y		A2	1.9994	$82.76
28405	Treatment of heel fracture	Y		A2	10.9093	$451.57
28406	Treatment of heel fracture	Y		A2	17.6585	$730.94
28415	Treat heel fracture	Y		A2	36.5127	$1,511.37
28420	Treat/graft heel fracture	Y		A2	28.3198	$1,172.24
28430	Treatment of ankle fracture	Y		P2	1.5579	$64.49
28435	Treatment of ankle fracture	Y		A2	1.9994	$82.76
28436	Treatment of ankle fracture	Y		A2	17.6585	$730.94
28445	Treat ankle fracture	Y		A2	26.9062	$1,113.73
28446	Osteochondral talus autogrft	Y		G2	46.114	$1,908.80
28450	Treat midfoot fracture, each	Y		P2	1.5579	$64.49
28455	Treat midfoot fracture, each	Y		P2	1.5579	$64.49
28456	Treat midfoot fracture	Y		A2	17.6585	$730.94

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28465	Treat midfoot fracture, each	Y		A2	26.9062	$1,113.73
28470	Treat metatarsal fracture	Y		P2	1.5579	$64.49
28475	Treat metatarsal fracture	Y		P2	1.5579	$64.49
28476	Treat metatarsal fracture	Y		A2	17.6585	$730.94
28485	Treat metatarsal fracture	Y		A2	28.3198	$1,172.24
28490	Treat big toe fracture	Y		P2	1.5579	$64.49
28495	Treat big toe fracture	Y		P2	1.5579	$64.49
28496	Treat big toe fracture	Y		A2	17.6585	$730.94
28505	Treat big toe fracture	Y		A2	18.4125	$762.15
28510	Treatment of toe fracture	Y		P3	1.4029	$58.07
28515	Treatment of toe fracture	Y		P2	1.5579	$64.49
28525	Treat toe fracture	Y		A2	18.4125	$762.15
28530	Treat sesamoid bone fracture	Y		P3	1.3505	$55.90
28531	Treat sesamoid bone fracture	Y		A2	18.4125	$762.15
28540	Treat foot dislocation	Y		P2	1.5579	$64.49
28545	Treat foot dislocation	Y		A2	16.3276	$675.85
28546	Treat foot dislocation	Y		A2	17.6585	$730.94
28555	Repair foot dislocation	Y		A2	26.1525	$1,082.53
28570	Treat foot dislocation	Y	CH	P3	2.0214	$83.67
28575	Treat foot dislocation	Y		A2	10.9093	$451.57
28576	Treat foot dislocation	Y		A2	18.4125	$762.15
28585	Repair foot dislocation	Y		A2	18.4125	$762.15
28600	Treat foot dislocation	Y		P2	1.5579	$64.49
28605	Treat foot dislocation	Y		A2	1.9994	$82.76
28606	Treat foot dislocation	Y		A2	17.6585	$730.94
28615	Repair foot dislocation	Y		A2	26.9062	$1,113.73
28630	Treat toe dislocation	Y	CH	P2	1.5579	$64.49
28635	Treat toe dislocation	Y		A2	11.5121	$476.52
28636	Treat toe dislocation	Y		A2	18.4125	$762.15
28645	Repair toe dislocation	Y		A2	18.4125	$762.15
28660	Treat toe dislocation	Y		P3	1.1154	$46.17
28665	Treat toe dislocation	Y		A2	11.5121	$476.52
28666	Treat toe dislocation	Y		A2	18.4125	$762.15
28675	Repair of toe dislocation	Y		A2	18.4125	$762.15
28705	Fusion of foot bones	Y		A2	30.4776	$1,261.56
28715	Fusion of foot bones	Y		A2	49.6403	$2,054.76
28725	Fusion of foot bones	Y		A2	30.4776	$1,261.56
28730	Fusion of foot bones	Y		A2	30.4776	$1,261.56

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28735	Fusion of foot bones	Y		A2	30.4776	$1,261.56
28737	Revision of foot bones	Y		A2	31.5022	$1,303.97
28740	Fusion of foot bones	Y		A2	30.4776	$1,261.56
28750	Fusion of big toe joint	Y		A2	30.4776	$1,261.56
28755	Fusion of big toe joint	Y		A2	17.9617	$743.49
28760	Fusion of big toe joint	Y		A2	30.4776	$1,261.56
28810	Amputation toe & metatarsal	Y		A2	15.7945	$653.78
28820	Amputation of toe	Y		A2	15.7945	$653.78
28825	Partial amputation of toe	Y		A2	15.7945	$653.78
28890	High energy eswt, plantar f	Y		P3	4.1737	$172.76
29000	Application of body cast	N		G2	1.0575	$43.77
29010	Application of body cast	N		P2	2.37	$98.10
29015	Application of body cast	N		P2	2.37	$98.10
29020	Application of body cast	N		G2	1.0575	$43.77
29025	Application of body cast	N		P2	1.0575	$43.77
29035	Application of body cast	N		P2	2.37	$98.10
29040	Application of body cast	N		G2	1.0575	$43.77
29044	Application of body cast	N		P2	2.37	$98.10
29046	Application of body cast	N		G2	2.37	$98.10
29049	Application of figure eight	N	CH	P3	0.9584	$39.67
29055	Application of shoulder cast	N		P2	2.37	$98.10
29058	Application of shoulder cast	N		P2	1.0575	$43.77
29065	Application of long arm cast	N		P3	1.1241	$46.53
29075	Application of forearm cast	N		P3	1.0804	$44.72
29085	Apply hand/wrist cast	N		P2	1.0575	$43.77
29086	Apply finger cast	N		P3	0.9062	$37.51
29105	Apply long arm splint	N		P3	0.9758	$40.39
29125	Apply forearm splint	N		P3	0.8451	$34.98
29126	Apply forearm splint	N		P3	0.8975	$37.15
29130	Application of finger splint	N		P3	0.3834	$15.87
29131	Application of finger splint	N		P3	0.5576	$23.08
29200	Strapping of chest	N		P3	0.5402	$22.36
29220	Strapping of low back	N		P3	0.5837	$24.16
29240	Strapping of shoulder	N		P3	0.61	$25.25
29260	Strapping of elbow or wrist	N		P3	0.5837	$24.16
29280	Strapping of hand or finger	N		P3	0.5926	$24.53
29305	Application of hip cast	N		P2	2.37	$98.10
29325	Application of hip casts	N		P2	2.37	$98.10

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29345	Application of long leg cast	N		P3	1.4725	$60.95
29355	Application of long leg cast	N		P3	1.4464	$59.87
29358	Apply long leg cast brace	N		P3	1.795	$74.30
29365	Application of long leg cast	N		P3	1.3942	$57.71
29405	Apply short leg cast	N		P3	1.0369	$42.92
29425	Apply short leg cast	N		P3	1.0543	$43.64
29435	Apply short leg cast	N		P3	1.3331	$55.18
29440	Addition of walker to cast	N		P3	0.5663	$23.44
29445	Apply rigid leg cast	N		P3	1.4029	$58.07
29450	Application of leg cast	N		P2	1.0575	$43.77
29505	Application, long leg splint	N		P3	0.941	$38.95
29515	Application lower leg splint	N		P3	0.8016	$33.18
29520	Strapping of hip	N		P3	0.575	$23.80
29530	Strapping of knee	N		P3	0.5837	$24.16
29540	Strapping of ankle and/or ft	N		P3	0.4356	$18.03
29550	Strapping of toes	N		P3	0.4443	$18.39
29580	Application of paste boot	N		P3	0.6013	$24.89
29590	Application of foot splint	N		P3	0.488	$20.20
29700	Removal/revision of cast	N		P3	0.8103	$33.54
29705	Removal/revision of cast	N		P3	0.6883	$28.49
29710	Removal/revision of cast	N		P3	1.2111	$50.13
29715	Removal/revision of cast	N		P2	1.0575	$43.77
29720	Repair of body cast	N		P3	1.0108	$41.84
29730	Windowing of cast	N		P3	0.6622	$27.41
29740	Wedging of cast	N		P3	0.9062	$37.51
29750	Wedging of clubfoot cast	N		P3	0.9497	$39.31
29800	Jaw arthroscopy/surgery	Y		A2	20.3484	$842.28
29804	Jaw arthroscopy/surgery	Y		A2	20.3484	$842.28
29805	Shoulder arthroscopy, dx	Y		A2	20.3484	$842.28
29806	Shoulder arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29807	Shoulder arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29819	Shoulder arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29820	Shoulder arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29821	Shoulder arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29822	Shoulder arthroscopy/surgery	Y		A2	20.3484	$842.28
29823	Shoulder arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29824	Shoulder arthroscopy/surgery	Y		A2	22.7865	$943.20
29825	Shoulder arthroscopy/surgery	Y		A2	30.0019	$1,241.87

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29826	Shoulder arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29827	Arthroscop rotator cuff repr	Y		A2	32.44	$1,342.79
29828	Arthroscopy biceps tenodesis	Y		G2	47.9898	$1,986.44
29830	Elbow arthroscopy	Y		A2	20.3484	$842.28
29834	Elbow arthroscopy/surgery	Y		A2	20.3484	$842.28
29835	Elbow arthroscopy/surgery	Y		A2	20.3484	$842.28
29836	Elbow arthroscopy/surgery	Y		A2	20.3484	$842.28
29837	Elbow arthroscopy/surgery	Y		A2	20.3484	$842.28
29838	Elbow arthroscopy/surgery	Y		A2	20.3484	$842.28
29840	Wrist arthroscopy	Y		A2	20.3484	$842.28
29843	Wrist arthroscopy/surgery	Y		A2	20.3484	$842.28
29844	Wrist arthroscopy/surgery	Y		A2	20.3484	$842.28
29845	Wrist arthroscopy/surgery	Y		A2	20.3484	$842.28
29846	Wrist arthroscopy/surgery	Y		A2	20.3484	$842.28
29847	Wrist arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29848	Wrist endoscopy/surgery	Y		A2	30.1126	$1,246.45
29850	Knee arthroscopy/surgery	Y		A2	21.7617	$900.78
29851	Knee arthroscopy/surgery	Y		A2	31.4155	$1,300.38
29855	Tibial arthroscopy/surgery	Y		A2	31.4155	$1,300.38
29856	Tibial arthroscopy/surgery	Y		A2	31.4155	$1,300.38
29860	Hip arthroscopy, dx	Y		A2	31.4155	$1,300.38
29861	Hip arthroscopy/surgery	Y		A2	31.4155	$1,300.38
29862	Hip arthroscopy/surgery	Y		A2	39.7664	$1,646.05
29863	Hip arthroscopy/surgery	Y		A2	31.4155	$1,300.38
29866	Autgrft implnt, knee w/scope	Y		G2	47.9898	$1,986.44
29870	Knee arthroscopy, dx	Y		A2	20.3484	$842.28
29871	Knee arthroscopy/drainage	Y		A2	20.3484	$842.28
29873	Knee arthroscopy/surgery	Y		A2	20.3484	$842.28
29874	Knee arthroscopy/surgery	Y		A2	20.3484	$842.28
29875	Knee arthroscopy/surgery	Y		A2	21.7617	$900.78
29876	Knee arthroscopy/surgery	Y		A2	21.7617	$900.78
29877	Knee arthroscopy/surgery	Y		A2	21.7617	$900.78
29879	Knee arthroscopy/surgery	Y		A2	20.3484	$842.28
29880	Knee arthroscopy/surgery	Y		A2	21.7617	$900.78
29881	Knee arthroscopy/surgery	Y		A2	21.7617	$900.78
29882	Knee arthroscopy/surgery	Y		A2	20.3484	$842.28
29883	Knee arthroscopy/surgery	Y		A2	20.3484	$842.28
29884	Knee arthroscopy/surgery	Y		A2	20.3484	$842.28

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HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
29885	Knee arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29886	Knee arthroscopy/surgery	Y		A2	20.3484	$842.28
29887	Knee arthroscopy/surgery	Y		A2	20.3484	$842.28
29888	Knee arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29889	Knee arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29891	Ankle arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29892	Ankle arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29893	Scope, plantar fasciotomy	Y		A2	25.3299	$1,048.48
29894	Ankle arthroscopy/surgery	Y		A2	20.3484	$842.28
29895	Ankle arthroscopy/surgery	Y		A2	20.3484	$842.28
29897	Ankle arthroscopy/surgery	Y		A2	20.3484	$842.28
29898	Ankle arthroscopy/surgery	Y		A2	20.3484	$842.28
29899	Ankle arthroscopy/surgery	Y		A2	30.0019	$1,241.87
29900	Mcp joint arthroscopy, dx	Y		A2	20.3484	$842.28
29901	Mcp joint arthroscopy, surg	Y		A2	20.3484	$842.28
29902	Mcp joint arthroscopy, surg	Y		A2	20.3484	$842.28
29904	Subtalar arthro w/fb rmvl	Y		G2	28.6825	$1,187.25
29905	Subtalar arthro w/exc	Y		G2	28.6825	$1,187.25
29906	Subtalar arthro w/deb	Y		G2	28.6825	$1,187.25
29907	Subtalar arthro w/fusion	Y		G2	47.9898	$1,986.44
30000	Drainage of nose lesion	Y		P2	3.2246	$133.48
30020	Drainage of nose lesion	Y		P2	3.2246	$133.48
30100	Intranasal biopsy	Y		P3	2.0912	$86.56
30110	Removal of nose polyp(s)	Y		P3	3.2327	$133.81
30115	Removal of nose polyp(s)	Y		A2	13.6586	$565.37
30117	Removal of intranasal lesion	Y		A2	14.4126	$596.58
30118	Removal of intranasal lesion	Y		A2	18.0767	$748.25
30120	Revision of nose	Y		A2	12.3277	$510.28
30124	Removal of nose lesion	Y		R2	7.3454	$304.05
30125	Removal of nose lesion	Y		A2	25.6688	$1,062.51
30130	Excise inferior turbinate	Y		A2	14.4126	$596.58
30140	Resect inferior turbinate	Y		A2	17.3227	$717.04
30150	Partial removal of nose	Y		A2	26.4228	$1,093.72
30160	Removal of nose	Y		A2	27.8361	$1,152.22
30200	Injection treatment of nose	Y		P3	1.6469	$68.17
30210	Nasal sinus therapy	Y		P3	2.0912	$86.56
30220	Insert nasal septal button	Y		A2	9.1397	$378.32
30300	Remove nasal foreign body	N		P2	0.6301	$26.08

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30310	Remove nasal foreign body	Y		A2	12.3277	$510.28
30320	Remove nasal foreign body	Y		A2	13.6586	$565.37
30400	Reconstruction of nose	Y		A2	27.8361	$1,152.22
30410	Reconstruction of nose	Y		A2	28.8609	$1,194.64
30420	Reconstruction of nose	Y		A2	28.8609	$1,194.64
30430	Revision of nose	Y		A2	18.0767	$748.25
30435	Revision of nose	Y		A2	28.8609	$1,194.64
30450	Revision of nose	Y		A2	32.1354	$1,330.18
30460	Revision of nose	Y		A2	32.1354	$1,330.18
30462	Revision of nose	Y		A2	36.187	$1,497.89
30465	Repair nasal stenosis	Y		A2	36.187	$1,497.89
30520	Repair of nasal septum	Y		A2	19.49	$806.75
30540	Repair nasal defect	Y		A2	28.8609	$1,194.64
30545	Repair nasal defect	Y		A2	28.8609	$1,194.64
30560	Release of nasal adhesions	Y		A2	3.3875	$140.22
30580	Repair upper jaw fistula	Y		A2	27.8361	$1,152.22
30600	Repair mouth/nose fistula	Y		A2	27.8361	$1,152.22
30620	Intranasal reconstruction	Y		A2	32.1354	$1,330.18
30630	Repair nasal septum defect	Y		A2	23.7893	$984.71
30801	Ablate inf turbinate, superf	Y		A2	7.595	$314.38
30802	Cauterization, inner nose	Y		A2	7.595	$314.38
30901	Control of nosebleed	Y		P2	1.0833	$44.84
30903	Control of nosebleed	Y		A2	1.3954	$57.76
30905	Control of nosebleed	Y		A2	1.3954	$57.76
30906	Repeat control of nosebleed	Y		A2	1.3954	$57.76
30915	Ligation, nasal sinus artery	Y		A2	18.5932	$769.63
30920	Ligation, upper jaw artery	Y		A2	19.3472	$800.84
30930	Ther fx, nasal inf turbinate	Y		A2	15.8259	$655.08
31000	Irrigation, maxillary sinus	Y	CH	P3	2.6925	$111.45
31002	Irrigation, sphenoid sinus	Y		R2	7.3454	$304.05
31020	Exploration, maxillary sinus	Y		A2	17.3227	$717.04
31030	Exploration, maxillary sinus	Y		A2	26.4228	$1,093.72
31032	Explore sinus, remove polyps	Y		A2	27.8361	$1,152.22
31040	Exploration behind upper jaw	Y		R2	24.1393	$999.20
31050	Exploration, sphenoid sinus	Y		A2	25.6688	$1,062.51
31051	Sphenoid sinus surgery	Y		A2	27.8361	$1,152.22
31070	Exploration of frontal sinus	Y		A2	17.3227	$717.04
31075	Exploration of frontal sinus	Y		A2	27.8361	$1,152.22

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31080	Removal of frontal sinus	Y		A2	27.8361	$1,152.22
31081	Removal of frontal sinus	Y		A2	27.8361	$1,152.22
31084	Removal of frontal sinus	Y		A2	27.8361	$1,152.22
31085	Removal of frontal sinus	Y		A2	27.8361	$1,152.22
31086	Removal of frontal sinus	Y		A2	27.8361	$1,152.22
31087	Removal of frontal sinus	Y		A2	27.8361	$1,152.22
31090	Exploration of sinuses	Y		A2	28.8609	$1,194.64
31200	Removal of ethmoid sinus	Y		A2	25.6688	$1,062.51
31201	Removal of ethmoid sinus	Y		A2	28.8609	$1,194.64
31205	Removal of ethmoid sinus	Y		A2	26.4228	$1,093.72
31231	Nasal endoscopy, dx	Y		P2	1.7629	$72.97
31233	Nasal/sinus endoscopy, dx	Y		A2	1.8989	$78.60
31235	Nasal/sinus endoscopy, dx	Y		A2	12.901	$534.01
31237	Nasal/sinus endoscopy, surg	Y		A2	14.2319	$589.10
31238	Nasal/sinus endoscopy, surg	Y		A2	12.901	$534.01
31239	Nasal/sinus endoscopy, surg	Y		A2	18.8314	$779.49
31240	Nasal/sinus endoscopy, surg	Y		A2	14.2319	$589.10
31254	Revision of ethmoid sinus	Y		A2	17.4179	$720.98
31255	Removal of ethmoid sinus	Y		A2	19.856	$821.90
31256	Exploration maxillary sinus	Y		A2	17.4179	$720.98
31267	Endoscopy, maxillary sinus	Y		A2	17.4179	$720.98
31276	Sinus endoscopy, surgical	Y		A2	17.4179	$720.98
31287	Nasal/sinus endoscopy, surg	Y		A2	17.4179	$720.98
31288	Nasal/sinus endoscopy, surg	Y		A2	17.4179	$720.98
31300	Removal of larynx lesion	Y		A2	20.5148	$849.17
31320	Diagnostic incision, larynx	Y		A2	25.6688	$1,062.51
31400	Revision of larynx	Y		A2	25.6688	$1,062.51
31420	Removal of epiglottis	Y		A2	25.6688	$1,062.51
31500	Insert emergency airway	N		G2	2.3579	$97.60
31502	Change of windpipe airway	N		G2	1.3557	$56.12
31505	Diagnostic laryngoscopy	Y		P2	0.801	$33.16
31510	Laryngoscopy with biopsy	Y		A2	14.2319	$589.10
31511	Remove foreign body, larynx	Y		A2	1.8989	$78.60
31512	Removal of larynx lesion	Y		A2	14.2319	$589.10
31513	Injection into vocal cord	Y		A2	1.8989	$78.60
31515	Laryngoscopy for aspiration	Y		A2	12.901	$534.01
31520	Dx laryngoscopy, newborn	Y		G2	1.7629	$72.97
31525	Dx laryngoscopy excl nb	Y		A2	12.901	$534.01

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31526	Dx laryngoscopy w/oper scope	Y		A2	16.6642	$689.78
31527	Laryngoscopy for treatment	Y		A2	15.333	$634.68
31528	Laryngoscopy and dilation	Y		A2	14.2319	$589.10
31529	Laryngoscopy and dilation	Y		A2	14.2319	$589.10
31530	Laryngoscopy w/fb removal	Y		A2	16.6642	$689.78
31531	Laryngoscopy w/fb & op scope	Y		A2	17.4179	$720.98
31535	Laryngoscopy w/biopsy	Y		A2	16.6642	$689.78
31536	Laryngoscopy w/bx & op scope	Y		A2	17.4179	$720.98
31540	Laryngoscopy w/exc of tumor	Y		A2	17.4179	$720.98
31541	Larynscop w/tumr exc + scope	Y		A2	18.8314	$779.49
31545	Remove vc lesion w/scope	Y		A2	18.8314	$779.49
31546	Remove vc lesion scope/graft	Y		A2	18.8314	$779.49
31560	Laryngoscop w/arytenoidectom	Y		A2	19.856	$821.90
31561	Larynscop, remve cart + scop	Y		A2	19.856	$821.90
31570	Laryngoscope w/vc inj	Y		A2	14.2319	$589.10
31571	Laryngoscop w/vc inj + scope	Y		A2	16.6642	$689.78
31575	Diagnostic laryngoscopy	Y	CH	P3	1.5162	$62.76
31576	Laryngoscopy with biopsy	Y		A2	16.6642	$689.78
31577	Remove foreign body, larynx	Y		A2	4.9226	$203.76
31578	Removal of larynx lesion	Y		A2	16.6642	$689.78
31579	Diagnostic laryngoscopy	Y		P3	2.7012	$111.81
31580	Revision of larynx	Y		A2	28.8609	$1,194.64
31582	Revision of larynx	Y		A2	28.8609	$1,194.64
31588	Revision of larynx	Y		A2	28.8609	$1,194.64
31590	Reinnervate larynx	Y		A2	28.8609	$1,194.64
31595	Larynx nerve surgery	Y		A2	25.6688	$1,062.51
31603	Incision of windpipe	Y		A2	7.595	$314.38
31605	Incision of windpipe	Y		G2	7.3454	$304.05
31611	Surgery/speech prosthesis	Y		A2	18.0767	$748.25
31612	Puncture/clear windpipe	Y		A2	15.9918	$661.95
31613	Repair windpipe opening	Y		A2	17.3227	$717.04
31614	Repair windpipe opening	Y		A2	25.6688	$1,062.51
31615	Visualization of windpipe	Y		A2	7.595	$314.38
31620	Endobronchial us add-on	N		N1		
31622	Dx bronchoscope/wash	Y		A2	8.895	$368.19
31623	Dx bronchoscope/brush	Y		A2	10.2259	$423.28
31624	Dx bronchoscope/lavage	Y		A2	10.2259	$423.28
31625	Bronchoscopy w/biopsy(s)	Y		A2	10.2259	$423.28

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31628	Bronchoscopy/lung bx, each	Y		A2	10.2259	$423.28
31629	Bronchoscopy/needle bx, each	Y		A2	10.2259	$423.28
31630	Bronchoscopy dilate/fx repr	Y		A2	17.523	$725.33
31631	Bronchoscopy, dilate w/stent	Y		A2	17.523	$725.33
31632	Bronchoscopy/lung bx, add'l	Y		G2	9.9453	$411.67
31633	Bronchoscopy/needle bx add'l	Y		G2	9.9453	$411.67
31635	Bronchoscopy w/fb removal	Y		A2	10.2259	$423.28
31636	Bronchoscopy, bronch stents	Y		A2	17.523	$725.33
31637	Bronchoscopy, stent add-on	Y		A2	8.895	$368.19
31638	Bronchoscopy, revise stent	Y		A2	17.523	$725.33
31640	Bronchoscopy w/tumor excise	Y		A2	17.523	$725.33
31641	Bronchoscopy, treat blockage	Y		A2	17.523	$725.33
31643	Diag bronchoscope/catheter	Y		A2	10.2259	$423.28
31645	Bronchoscopy, clear airways	Y		A2	8.895	$368.19
31646	Bronchoscopy, reclear airway	Y		A2	8.895	$368.19
31656	Bronchoscopy, inj for x-ray	Y		A2	8.895	$368.19
31715	Injection for bronchus x-ray	N		N1		
31717	Bronchial brush biopsy	Y		A2	4.9226	$203.76
31720	Clearance of airways	N		A2	0.7538	$31.20
31730	Intro, windpipe wire/tube	Y		A2	4.9226	$203.76
31750	Repair of windpipe	Y		A2	28.8609	$1,194.64
31755	Repair of windpipe	Y		A2	25.6688	$1,062.51
31820	Closure of windpipe lesion	Y		A2	12.3277	$510.28
31825	Repair of windpipe defect	Y		A2	17.3227	$717.04
31830	Revise windpipe scar	Y		A2	17.3227	$717.04
32400	Needle biopsy chest lining	Y		A2	8.5923	$355.66
32405	Biopsy, lung or mediastinum	Y		A2	8.5923	$355.66
32420	Puncture/clear lung	Y		A2	5.2248	$216.27
32421	Thoracentesis for aspiration	Y		A2	5.2248	$216.27
32422	Thoracentesis w/tube insert	Y		G2	5.2015	$215.31
32550	Insert pleural cath	Y		G2	29.1233	$1,205.50
32960	Therapeutic pneumothorax	Y		G2	5.2015	$215.31
32998	Perq rf ablate tx, pul tumor	Y		G2	45.3434	$1,876.90
33010	Drainage of heart sac	Y		A2	5.2248	$216.27
33011	Repeat drainage of heart sac	Y		A2	5.2248	$216.27
33206	Insertion of heart pacemaker	Y		J8	167.6312	$6,938.76
33207	Insertion of heart pacemaker	Y		J8	167.6312	$6,938.76
33208	Insertion of heart pacemaker	Y		J8	207.9103	$8,606.03

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33210	Insertion of heart electrode	Y	CH	G2	49.2255	$2,037.59
33211	Insertion of heart electrode	Y	CH	G2	49.2255	$2,037.59
33212	Insertion of pulse generator	Y		H8	131.6503	$5,449.40
33213	Insertion of pulse generator	Y		H8	151.9527	$6,289.78
33214	Upgrade of pacemaker system	Y		J8	207.9103	$8,606.03
33215	Reposition pacing-defib lead	Y		G2	21.5762	$893.10
33216	Insert lead pace-defib, one	Y	CH	G2	49.2255	$2,037.59
33217	Insert lead pace-defib, dual	Y	CH	G2	49.2255	$2,037.59
33218	Repair lead pace-defib, one	Y		G2	21.5762	$893.10
33220	Repair lead pace-defib, dual	Y		G2	21.5762	$893.10
33222	Revise pocket, pacemaker	Y		A2	13.0418	$539.84
33223	Revise pocket, pacing-defib	Y		A2	13.0418	$539.84
33224	Insert pacing lead & connect	Y		J8	196.2479	$8,123.29
33225	L ventric pacing lead add-on	Y		J8	196.2479	$8,123.29
33226	Reposition l ventric lead	Y		G2	21.5762	$893.10
33233	Removal of pacemaker system	Y		A2	16.0414	$664.00
33234	Removal of pacemaker system	Y		G2	21.5762	$893.10
33235	Removal pacemaker electrode	Y		G2	21.5762	$893.10
33240	Insert pulse generator	Y		J8	489.196	$20,249.29
33241	Remove pulse generator	Y		G2	21.5762	$893.10
33249	Eltrd/insert pace-defib	Y		J8	652.8693	$27,024.22
33282	Implant pat-active ht record	N		J8	103.2228	$4,272.70
33284	Remove pat-active ht record	Y		G2	8.051	$333.26
33508	Endoscopic vein harvest	N		N1		
34490	Removal of vein clot	Y	CH	G2	39.3079	$1,627.07
35188	Repair blood vessel lesion	Y		A2	27.0744	$1,120.69
35207	Repair blood vessel lesion	Y		A2	27.0744	$1,120.69
35473	Repair arterial blockage	Y		G2	47.1543	$1,951.86
35476	Repair venous blockage	Y		G2	47.1543	$1,951.86
35492	Atherectomy, percutaneous	Y		G2	88.0088	$3,642.95
35572	Harvest femoropopliteal vein	N		N1		
35761	Exploration of artery/vein	Y		G2	28.3113	$1,171.89
35875	Removal of clot in graft	Y		A2	35.4253	$1,466.36
35876	Removal of clot in graft	Y		A2	35.4253	$1,466.36
36000	Place needle in vein	N		N1		
36002	Pseudoaneurysm injection trt	N		G2	2.2609	$93.59
36005	Injection ext venography	N		N1		
36010	Place catheter in vein	N		N1		

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HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
36011	Place catheter in vein	N		N1		
36012	Place catheter in vein	N		N1		
36013	Place catheter in artery	N		N1		
36014	Place catheter in artery	N		N1		
36015	Place catheter in artery	N		N1		
36100	Establish access to artery	N		N1		
36120	Establish access to artery	N		N1		
36140	Establish access to artery	N		N1		
36145	Artery to vein shunt	N		N1		
36160	Establish access to aorta	N		N1		
36200	Place catheter in aorta	N		N1		
36215	Place catheter in artery	N		N1		
36216	Place catheter in artery	N		N1		
36217	Place catheter in artery	N		N1		
36218	Place catheter in artery	N		N1		
36245	Place catheter in artery	N		N1		
36246	Place catheter in artery	N		N1		
36247	Place catheter in artery	N		N1		
36248	Place catheter in artery	N		N1		
36260	Insertion of infusion pump	Y		A2	20.5105	$848.99
36261	Revision of infusion pump	Y		A2	16.0414	$664.00
36262	Removal of infusion pump	Y		A2	14.7102	$608.90
36400	Bl draw < 3 yrs fem/jugular	N		N1		
36405	Bl draw < 3 yrs scalp vein	N		N1		
36406	Bl draw < 3 yrs other vein	N		N1		
36410	Non-routine bl draw > 3 yrs	N		N1		
36416	Capillary blood draw	N		N1		
36420	Vein access cutdown < 1 yr	N		G2	0.2132	$8.82
36425	Vein access cutdown > 1 yr	N		R2	0.2132	$8.82
36430	Blood transfusion service	N		P3	0.819	$33.90
36440	Bl push transfuse, 2 yr or <	N		R2	3.2709	$135.39
36450	Bl exchange/transfuse, nb	N		R2	3.2709	$135.39
36455	Bl exchange/transfuse non-nb	N	CH	G2	3.2709	$135.39
36468	Injection(s), spider veins	Y		R2	0.8075	$33.42
36469	Injection(s), spider veins	Y		R2	0.8075	$33.42
36470	Injection therapy of vein	Y		P2	0.8075	$33.42
36471	Injection therapy of veins	Y		P2	0.8075	$33.42
36475	Endovenous rf, 1st vein	Y		A2	37.1222	$1,536.60

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36476	Endovenous rf, vein add-on	Y		A2	29.1114	$1,205.01
36478	Endovenous laser, 1st vein	Y		A2	29.1114	$1,205.01
36479	Endovenous laser vein addon	Y		A2	29.1114	$1,205.01
36481	Insertion of catheter, vein	N		N1		
36500	Insertion of catheter, vein	N		N1		
36510	Insertion of catheter, vein	N		N1		
36511	Apheresis wbc	N		G2	11.214	$464.18
36512	Apheresis rbc	N		G2	11.214	$464.18
36513	Apheresis platelets	N		G2	11.214	$464.18
36514	Apheresis plasma	N		G2	11.214	$464.18
36515	Apheresis, adsorp/reinfuse	N	CH	P2	30.0199	$1,242.61
36516	Apheresis, selective	N	CH	P2	30.0199	$1,242.61
36522	Photopheresis	N		G2	30.0199	$1,242.61
36555	Insert non-tunnel cv cath	Y		A2	9.3173	$385.67
36556	Insert non-tunnel cv cath	Y		A2	9.3173	$385.67
36557	Insert tunneled cv cath	Y		A2	17.4008	$720.27
36558	Insert tunneled cv cath	Y		A2	17.4008	$720.27
36560	Insert tunneled cv cath	Y		A2	20.5105	$848.99
36561	Insert tunneled cv cath	Y		A2	20.5105	$848.99
36563	Insert tunneled cv cath	Y		A2	20.5105	$848.99
36565	Insert tunneled cv cath	Y		A2	20.5105	$848.99
36566	Insert tunneled cv cath	Y	CH	A2	20.5105	$848.99
36568	Insert picc cath	Y		A2	9.3173	$385.67
36569	Insert picc cath	Y		A2	9.3173	$385.67
36570	Insert picvad cath	Y		A2	18.1545	$751.47
36571	Insert picvad cath	Y		A2	18.1545	$751.47
36575	Repair tunneled cv cath	Y		A2	7.4938	$310.19
36576	Repair tunneled cv cath	Y		A2	10.6482	$440.76
36578	Replace tunneled cv cath	Y		A2	17.4008	$720.27
36580	Replace cvad cath	Y		A2	9.3173	$385.67
36581	Replace tunneled cv cath	Y		A2	17.4008	$720.27
36582	Replace tunneled cv cath	Y		A2	20.5105	$848.99
36583	Replace tunneled cv cath	Y		A2	20.5105	$848.99
36584	Replace picc cath	Y		A2	9.3173	$385.67
36585	Replace picvad cath	Y		A2	18.1545	$751.47
36589	Removal tunneled cv cath	Y		A2	6.1629	$255.10
36590	Removal tunneled cv cath	Y		A2	9.3173	$385.67
36591	Draw blood off venous device	N		N1		

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36592	Collect blood from picc	N		N1		
36593	Declot vascular device	Y		P3	0.6187	$25.61
36595	Mech remov tunneled cv cath	Y		G2	24.2949	$1,005.64
36596	Mech remov tunneled cv cath	Y		G2	10.7898	$446.62
36597	Reposition venous catheter	Y		G2	10.7898	$446.62
36598	Inj w/fluor, eval cv device	Y		P3	1.9953	$82.59
36600	Withdrawal of arterial blood	N		N1		
36620	Insertion catheter, artery	N		N1		
36625	Insertion catheter, artery	N		N1		
36640	Insertion catheter, artery	Y		A2	18.4256	$762.69
36680	Insert needle, bone cavity	Y		G2	1.3967	$57.81
36800	Insertion of cannula	Y		A2	22.0796	$913.94
36810	Insertion of cannula	Y		A2	22.0796	$913.94
36815	Insertion of cannula	Y		A2	22.0796	$913.94
36818	Av fuse, uppr arm, cephalic	Y		A2	25.6611	$1,062.19
36819	Av fuse, uppr arm, basilic	Y		A2	25.6611	$1,062.19
36820	Av fusion/forearm vein	Y		A2	25.6611	$1,062.19
36821	Av fusion direct any site	Y		A2	25.6611	$1,062.19
36825	Artery-vein autograft	Y		A2	27.0744	$1,120.69
36830	Artery-vein nonautograft	Y		A2	27.0744	$1,120.69
36831	Open thrombect av fistula	Y		A2	35.4253	$1,466.36
36832	Av fistula revision, open	Y		A2	27.0744	$1,120.69
36833	Av fistula revision	Y		A2	27.0744	$1,120.69
36834	Repair a-v aneurysm	Y		A2	25.6611	$1,062.19
36835	Artery to vein shunt	Y		A2	23.4931	$972.45
36860	External cannula declotting	Y		A2	2.6963	$111.61
36861	Cannula declotting	Y		A2	22.0796	$913.94
36870	Percut thrombect av fistula	Y		A2	38.6138	$1,598.34
37184	Prim art mech thrombectomy	Y		G2	39.3079	$1,627.07
37185	Prim art m-thrombect add-on	Y		G2	39.3079	$1,627.07
37186	Sec art m-thrombect add-on	Y		G2	39.3079	$1,627.07
37187	Venous mech thrombectomy	Y		G2	39.3079	$1,627.07
37188	Venous m-thrombectomy add-on	Y		G2	39.3079	$1,627.07
37200	Transcatheter biopsy	Y		G2	29.0069	$1,200.68
37203	Transcatheter retrieval	Y		G2	29.0069	$1,200.68
37250	Iv us first vessel add-on	N		N1		
37251	Iv us each add vessel add-on	N		N1		
37500	Endoscopy ligate perf veins	Y		A2	27.358	$1,132.43

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37607	Ligation of a-v fistula	Y		A2	19.3472	$800.84
37609	Temporal artery procedure	Y		A2	13.0039	$538.27
37650	Revision of major vein	Y		A2	18.5932	$769.63
37700	Revise leg vein	Y		A2	18.5932	$769.63
37718	Ligate/strip short leg vein	Y		A2	19.3472	$800.84
37722	Ligate/strip long leg vein	Y		A2	27.358	$1,132.43
37735	Removal of leg veins/lesion	Y		A2	27.358	$1,132.43
37760	Ligation, leg veins, open	Y		A2	19.3472	$800.84
37765	Phleb veins - extrem - to 20	Y		R2	26.6801	$1,104.37
37766	Phleb veins - extrem 20+	Y		R2	26.6801	$1,104.37
37780	Revision of leg vein	Y		A2	19.3472	$800.84
37785	Ligate/divide/excise vein	Y		A2	19.3472	$800.84
37790	Penile venous occlusion	Y		A2	23.3462	$966.37
38200	Injection for spleen x-ray	N		N1		
38204	BI donor search management	N		N1		
38205	Harvest allogenic stem cells	N		G2	11.214	$464.18
38206	Harvest auto stem cells	N		G2	11.214	$464.18
38220	Bone marrow aspiration	Y		P3	2.5705	$106.40
38221	Bone marrow biopsy	Y		P3	2.6925	$111.45
38230	Bone marrow collection	N		G2	30.0199	$1,242.61
38241	Bone marrow/stem transplant	N		G2	30.0199	$1,242.61
38242	Lymphocyte infuse transplant	N		R2	11.214	$464.18
38300	Drainage, lymph node lesion	Y		A2	10.0631	$416.54
38305	Drainage, lymph node lesion	Y		A2	14.7056	$608.71
38308	Incision of lymph channels	Y		A2	16.8031	$695.53
38500	Biopsy/removal, lymph nodes	Y		A2	16.8031	$695.53
38505	Needle biopsy, lymph nodes	Y		A2	6.4289	$266.11
38510	Biopsy/removal, lymph nodes	Y		A2	16.8031	$695.53
38520	Biopsy/removal, lymph nodes	Y		A2	16.8031	$695.53
38525	Biopsy/removal, lymph nodes	Y		A2	16.8031	$695.53
38530	Biopsy/removal, lymph nodes	Y		A2	16.8031	$695.53
38542	Explore deep node(s), neck	Y		A2	28.2688	$1,170.13
38550	Removal, neck/armpit lesion	Y		A2	17.5571	$726.74
38555	Removal, neck/armpit lesion	Y		A2	18.9704	$785.24
38570	Laparoscopy, lymph node biop	Y		A2	38.3565	$1,587.69
38571	Laparoscopy, lymphadenectomy	Y		A2	49.8625	$2,063.96
38572	Laparoscopy, lymphadenectomy	Y		A2	38.3565	$1,587.69
38700	Removal of lymph nodes, neck	Y		G2	23.0998	$956.17

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38740	Remove armpit lymph nodes	Y		A2	28.2688	$1,170.13
38745	Remove armpit lymph nodes	Y		A2	30.4361	$1,259.84
38760	Remove groin lymph nodes	Y		A2	16.8031	$695.53
38790	Inject for lymphatic x-ray	N		N1		
38792	Identify sentinel node	N		N1		
38794	Access thoracic lymph duct	N		N1		
40490	Biopsy of lip	Y		P3	1.7165	$71.05
40500	Partial excision of lip	Y		A2	13.6586	$565.37
40510	Partial excision of lip	Y		A2	17.3227	$717.04
40520	Partial excision of lip	Y		A2	13.6586	$565.37
40525	Reconstruct lip with flap	Y		A2	17.3227	$717.04
40527	Reconstruct lip with flap	Y		A2	17.3227	$717.04
40530	Partial removal of lip	Y		A2	17.3227	$717.04
40650	Repair lip	Y		A2	9.1397	$378.32
40652	Repair lip	Y		A2	9.1397	$378.32
40654	Repair lip	Y		A2	9.1397	$378.32
40700	Repair cleft lip/nasal	Y		A2	32.1354	$1,330.18
40701	Repair cleft lip/nasal	Y		A2	32.1354	$1,330.18
40702	Repair cleft lip/nasal	Y		R2	40.8314	$1,690.13
40720	Repair cleft lip/nasal	Y		A2	32.1354	$1,330.18
40761	Repair cleft lip/nasal	Y		A2	26.4228	$1,093.72
40800	Drainage of mouth lesion	Y		P2	1.3776	$57.02
40801	Drainage of mouth lesion	Y		A2	8.9259	$369.47
40804	Removal, foreign body, mouth	N		P2	0.6301	$26.08
40805	Removal, foreign body, mouth	Y		P3	4.2609	$176.37
40806	Incision of lip fold	Y		P3	1.9605	$81.15
40808	Biopsy of mouth lesion	Y	CH	P3	2.9102	$120.46
40810	Excision of mouth lesion	Y		P3	3.0148	$124.79
40812	Excise/repair mouth lesion	Y		P3	3.7816	$156.53
40814	Excise/repair mouth lesion	Y		A2	13.6586	$565.37
40816	Excision of mouth lesion	Y		A2	17.3227	$717.04
40818	Excise oral mucosa for graft	Y		A2	3.3875	$140.22
40819	Excise lip or cheek fold	Y		A2	7.595	$314.38
40820	Treatment of mouth lesion	Y		P3	4.3478	$179.97
40830	Repair mouth laceration	Y		G2	3.2246	$133.48
40831	Repair mouth laceration	Y		A2	7.595	$314.38
40840	Reconstruction of mouth	Y		A2	17.3227	$717.04
40842	Reconstruction of mouth	Y		A2	18.0767	$748.25

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40843	Reconstruction of mouth	Y		A2	18.0767	$748.25
40844	Reconstruction of mouth	Y		A2	28.8609	$1,194.64
40845	Reconstruction of mouth	Y		A2	28.8609	$1,194.64
41000	Drainage of mouth lesion	Y		P3	2.161	$89.45
41005	Drainage of mouth lesion	Y		A2	3.3875	$140.22
41006	Drainage of mouth lesion	Y		A2	15.9918	$661.95
41007	Drainage of mouth lesion	Y		A2	12.3277	$510.28
41008	Drainage of mouth lesion	Y		A2	12.3277	$510.28
41009	Drainage of mouth lesion	Y		A2	3.3875	$140.22
41010	Incision of tongue fold	Y		A2	7.595	$314.38
41015	Drainage of mouth lesion	Y		A2	3.3875	$140.22
41016	Drainage of mouth lesion	Y		A2	7.595	$314.38
41017	Drainage of mouth lesion	Y		A2	7.595	$314.38
41018	Drainage of mouth lesion	Y		A2	7.595	$314.38
41019	Place needles h&n for rt	Y		G2	24.1393	$999.20
41100	Biopsy of tongue	Y		P3	2.2741	$94.13
41105	Biopsy of tongue	Y		P3	2.248	$93.05
41108	Biopsy of floor of mouth	Y		P3	2.0825	$86.20
41110	Excision of tongue lesion	Y		P3	3.0148	$124.79
41112	Excision of tongue lesion	Y		A2	13.6586	$565.37
41113	Excision of tongue lesion	Y		A2	13.6586	$565.37
41114	Excision of tongue lesion	Y		A2	17.3227	$717.04
41115	Excision of tongue fold	Y		P3	3.5115	$145.35
41116	Excision of mouth lesion	Y		A2	12.3277	$510.28
41120	Partial removal of tongue	Y		A2	20.5148	$849.17
41250	Repair tongue laceration	Y		A2	2.3168	$95.90
41251	Repair tongue laceration	Y		A2	3.3875	$140.22
41252	Repair tongue laceration	Y		A2	8.9259	$369.47
41500	Fixation of tongue	Y		A2	15.9918	$661.95
41510	Tongue to lip surgery	Y		A2	12.3277	$510.28
41520	Reconstruction, tongue fold	Y		A2	8.9259	$369.47
41530	Tongue base vol reduction	Y	NI	G2	16.8109	$695.85
41800	Drainage of gum lesion	Y		A2	1.7307	$71.64
41805	Removal foreign body, gum	Y		P3	3.7468	$155.09
41806	Removal foreign body,jawbone	Y		P3	4.6179	$191.15
41820	Excision, gum, each quadrant	Y		R2	7.3454	$304.05
41821	Excision of gum flap	Y		G2	7.3454	$304.05
41822	Excision of gum lesion	Y		P3	3.825	$158.33

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41823	Excision of gum lesion	Y		P3	5.5765	$230.83
41825	Excision of gum lesion	Y		P3	3.0669	$126.95
41826	Excision of gum lesion	Y		P3	3.8601	$159.78
41827	Excision of gum lesion	Y		A2	17.3227	$717.04
41828	Excision of gum lesion	Y		P3	3.4854	$144.27
41830	Removal of gum tissue	Y		P3	4.9491	$204.86
41850	Treatment of gum lesion	Y		R2	16.8109	$695.85
41870	Gum graft	Y		G2	24.1393	$999.20
41872	Repair gum	Y		P3	4.9491	$204.86
41874	Repair tooth socket	Y		P3	4.7747	$197.64
42000	Drainage mouth roof lesion	Y		A2	3.3875	$140.22
42100	Biopsy roof of mouth	Y		P3	1.9344	$80.07
42104	Excision lesion, mouth roof	Y		P3	2.8754	$119.02
42106	Excision lesion, mouth roof	Y		P3	3.6074	$149.32
42107	Excision lesion, mouth roof	Y		A2	17.3227	$717.04
42120	Remove palate/lesion	Y		A2	27.8361	$1,152.22
42140	Excision of uvula	Y		A2	8.9259	$369.47
42145	Repair palate, pharynx/uvula	Y		A2	20.5148	$849.17
42160	Treatment mouth roof lesion	Y		P3	3.4156	$141.38
42180	Repair palate	Y		A2	3.3875	$140.22
42182	Repair palate	Y		A2	25.6688	$1,062.51
42200	Reconstruct cleft palate	Y		A2	28.8609	$1,194.64
42205	Reconstruct cleft palate	Y		A2	28.8609	$1,194.64
42210	Reconstruct cleft palate	Y		A2	28.8609	$1,194.64
42215	Reconstruct cleft palate	Y		A2	32.1354	$1,330.18
42220	Reconstruct cleft palate	Y		A2	28.8609	$1,194.64
42226	Lengthening of palate	Y		A2	28.8609	$1,194.64
42235	Repair palate	Y		A2	16.8507	$697.50
42260	Repair nose to lip fistula	Y		A2	19.49	$806.75
42280	Preparation, palate mold	Y		P3	1.882	$77.90
42281	Insertion, palate prosthesis	Y		G2	16.8109	$695.85
42300	Drainage of salivary gland	Y		A2	12.3277	$510.28
42305	Drainage of salivary gland	Y		A2	13.6586	$565.37
42310	Drainage of salivary gland	Y		A2	3.3875	$140.22
42320	Drainage of salivary gland	Y		A2	3.3875	$140.22
42330	Removal of salivary stone	Y		P3	2.9102	$120.46
42335	Removal of salivary stone	Y		P3	4.8271	$199.81
42340	Removal of salivary stone	Y		A2	13.6586	$565.37

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HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
42400	Biopsy of salivary gland	Y		P3	1.6382	$67.81
42405	Biopsy of salivary gland	Y		A2	13.6586	$565.37
42408	Excision of salivary cyst	Y		A2	14.4126	$596.58
42409	Drainage of salivary cyst	Y		A2	14.4126	$596.58
42410	Excise parotid gland/lesion	Y		A2	26.4228	$1,093.72
42415	Excise parotid gland/lesion	Y		A2	32.1354	$1,330.18
42420	Excise parotid gland/lesion	Y		A2	32.1354	$1,330.18
42425	Excise parotid gland/lesion	Y		A2	32.1354	$1,330.18
42440	Excise submaxillary gland	Y		A2	26.4228	$1,093.72
42450	Excise sublingual gland	Y		A2	17.3227	$717.04
42500	Repair salivary duct	Y		A2	18.0767	$748.25
42505	Repair salivary duct	Y		A2	27.8361	$1,152.22
42507	Parotid duct diversion	Y		A2	26.4228	$1,093.72
42508	Parotid duct diversion	Y		A2	27.8361	$1,152.22
42509	Parotid duct diversion	Y		A2	27.8361	$1,152.22
42510	Parotid duct diversion	Y		A2	27.8361	$1,152.22
42550	Injection for salivary x-ray	N		N1		
42600	Closure of salivary fistula	Y		A2	12.3277	$510.28
42650	Dilation of salivary duct	Y		P3	1.0717	$44.36
42660	Dilation of salivary duct	Y		P3	1.2548	$51.94
42665	Ligation of salivary duct	Y		A2	23.7893	$984.71
42700	Drainage of tonsil abscess	Y		A2	3.3875	$140.22
42720	Drainage of throat abscess	Y		A2	12.3277	$510.28
42725	Drainage of throat abscess	Y		A2	25.6688	$1,062.51
42800	Biopsy of throat	Y		P3	2.0738	$85.84
42802	Biopsy of throat	Y		A2	12.3277	$510.28
42804	Biopsy of upper nose/throat	Y		A2	12.3277	$510.28
42806	Biopsy of upper nose/throat	Y		A2	17.3227	$717.04
42808	Excise pharynx lesion	Y		A2	13.6586	$565.37
42809	Remove pharynx foreign body	N		G2	0.6301	$26.08
42810	Excision of neck cyst	Y		A2	18.0767	$748.25
42815	Excision of neck cyst	Y		A2	28.8609	$1,194.64
42820	Remove tonsils and adenoids	Y		A2	18.0767	$748.25
42821	Remove tonsils and adenoids	Y		A2	20.5148	$849.17
42825	Removal of tonsils	Y		A2	19.49	$806.75
42826	Removal of tonsils	Y		A2	19.49	$806.75
42830	Removal of adenoids	Y		A2	19.49	$806.75
42831	Removal of adenoids	Y		A2	19.49	$806.75

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42835	Removal of adenoids	Y		A2	19.49	$806.75
42836	Removal of adenoids	Y		A2	19.49	$806.75
42860	Excision of tonsil tags	Y		A2	18.0767	$748.25
42870	Excision of lingual tonsil	Y		A2	18.0767	$748.25
42890	Partial removal of pharynx	Y		A2	32.1354	$1,330.18
42892	Revision of pharyngeal walls	Y		A2	32.1354	$1,330.18
42900	Repair throat wound	Y		A2	7.595	$314.38
42950	Reconstruction of throat	Y		A2	17.3227	$717.04
42955	Surgical opening of throat	Y		A2	17.3227	$717.04
42960	Control throat bleeding	Y		A2	1.3954	$57.76
42962	Control throat bleeding	Y		A2	25.6688	$1,062.51
42970	Control nose/throat bleeding	Y		R2	1.0833	$44.84
42972	Control nose/throat bleeding	Y		A2	14.4126	$596.58
43030	Throat muscle surgery	Y		G2	16.8109	$695.85
43200	Esophagus endoscopy	Y		A2	8.1407	$336.97
43201	Esoph scope w/submucous inj	Y		A2	8.1407	$336.97
43202	Esophagus endoscopy, biopsy	Y		A2	8.1407	$336.97
43204	Esoph scope w/sclerosis inj	Y		A2	8.1407	$336.97
43205	Esophagus endoscopy/ligation	Y		A2	8.1407	$336.97
43215	Esophagus endoscopy	Y		A2	8.1407	$336.97
43216	Esophagus endoscopy/lesion	Y		A2	8.1407	$336.97
43217	Esophagus endoscopy	Y		A2	8.1407	$336.97
43219	Esophagus endoscopy	Y		A2	16.4525	$681.02
43220	Esoph endoscopy, dilation	Y		A2	8.1407	$336.97
43226	Esoph endoscopy, dilation	Y		A2	8.1407	$336.97
43227	Esoph endoscopy, repair	Y		A2	9.4719	$392.07
43228	Esoph endoscopy, ablation	Y		A2	17.6264	$729.61
43231	Esoph endoscopy w/us exam	Y		A2	9.4719	$392.07
43232	Esoph endoscopy w/us fn bx	Y		A2	9.4719	$392.07
43234	Upper gi endoscopy, exam	Y		A2	8.1407	$336.97
43235	Uppr gi endoscopy, diagnosis	Y		A2	8.1407	$336.97
43236	Uppr gi scope w/submuc inj	Y		A2	9.4719	$392.07
43237	Endoscopic us exam, esoph	Y		A2	9.4719	$392.07
43238	Uppr gi endoscopy w/us fn bx	Y		A2	9.4719	$392.07
43239	Upper gi endoscopy, biopsy	Y		A2	9.4719	$392.07
43240	Esoph endoscope w/drain cyst	Y		A2	9.4719	$392.07
43241	Upper gi endoscopy with tube	Y		A2	9.4719	$392.07
43242	Uppr gi endoscopy w/us fn bx	Y		A2	9.4719	$392.07

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43243	Upper gi endoscopy & inject	Y		A2	9.4719	$392.07
43244	Upper gi endoscopy/ligation	Y		A2	9.4719	$392.07
43245	Uppr gi scope dilate strictr	Y		A2	9.4719	$392.07
43246	Place gastrostomy tube	Y		A2	9.4719	$392.07
43247	Operative upper gi endoscopy	Y		A2	9.4719	$392.07
43248	Uppr gi endoscopy/guide wire	Y		A2	9.4719	$392.07
43249	Esoph endoscopy, dilation	Y		A2	9.4719	$392.07
43250	Upper gi endoscopy/tumor	Y		A2	9.4719	$392.07
43251	Operative upper gi endoscopy	Y		A2	9.4719	$392.07
43255	Operative upper gi endoscopy	Y		A2	9.4719	$392.07
43256	Uppr gi endoscopy w/stent	Y		A2	18.5374	$767.32
43257	Uppr gi scope w/thrml txmnt	Y		A2	18.3804	$760.82
43258	Operative upper gi endoscopy	Y		A2	10.2256	$423.27
43259	Endoscopic ultrasound exam	Y		A2	10.2256	$423.27
43260	Endo cholangiopancreatograph	Y		A2	15.9459	$660.05
43261	Endo cholangiopancreatograph	Y		A2	15.9459	$660.05
43262	Endo cholangiopancreatograph	Y		A2	15.9459	$660.05
43263	Endo cholangiopancreatograph	Y		A2	15.9459	$660.05
43264	Endo cholangiopancreatograph	Y		A2	15.9459	$660.05
43265	Endo cholangiopancreatograph	Y		A2	15.9459	$660.05
43267	Endo cholangiopancreatograph	Y		A2	15.9459	$660.05
43268	Endo cholangiopancreatograph	Y		A2	17.7837	$736.12
43269	Endo cholangiopancreatograph	Y		A2	17.7837	$736.12
43271	Endo cholangiopancreatograph	Y		A2	15.9459	$660.05
43272	Endo cholangiopancreatograph	Y		A2	15.9459	$660.05
43273	Endoscopic pancreatoscopy	Y	NI	G2	21.3854	$885.21
43450	Dilate esophagus	Y		A2	7.1196	$294.70
43453	Dilate esophagus	Y		A2	7.1196	$294.70
43456	Dilate esophagus	Y		A2	7.1478	$295.87
43458	Dilate esophagus	Y		A2	8.1693	$338.15
43600	Biopsy of stomach	Y		A2	8.1407	$336.97
43653	Laparoscopy, gastrostomy	Y		A2	38.3565	$1,587.69
43760	Change gastrostomy tube	Y		A2	3.9483	$163.43
43761	Reposition gastrostomy tube	Y		A2	8.1407	$336.97
43870	Repair stomach opening	Y		A2	8.1407	$336.97
43886	Revise gastric port, open	Y		G2	20.5411	$850.26
43887	Remove gastric port, open	Y		G2	4.3203	$178.83
43888	Change gastric port, open	Y		G2	20.5411	$850.26

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44100	Biopsy of bowel	Y		A2	8.1407	$336.97
44312	Revision of ileostomy	Y		A2	14.1927	$587.48
44340	Revision of colostomy	Y		A2	16.2776	$673.78
44360	Small bowel endoscopy	Y		A2	9.9203	$410.63
44361	Small bowel endoscopy/biopsy	Y		A2	9.9203	$410.63
44363	Small bowel endoscopy	Y		A2	9.9203	$410.63
44364	Small bowel endoscopy	Y		A2	9.9203	$410.63
44365	Small bowel endoscopy	Y		A2	9.9203	$410.63
44366	Small bowel endoscopy	Y		A2	9.9203	$410.63
44369	Small bowel endoscopy	Y		A2	9.9203	$410.63
44370	Small bowel endoscopy/stent	Y		A2	28.3019	$1,171.50
44372	Small bowel endoscopy	Y		A2	9.9203	$410.63
44373	Small bowel endoscopy	Y		A2	9.9203	$410.63
44376	Small bowel endoscopy	Y		A2	9.9203	$410.63
44377	Small bowel endoscopy/biopsy	Y		A2	9.9203	$410.63
44378	Small bowel endoscopy	Y		A2	9.9203	$410.63
44379	S bowel endoscope w/stent	Y		A2	28.3019	$1,171.50
44380	Small bowel endoscopy	Y		A2	8.5891	$355.53
44382	Small bowel endoscopy	Y		A2	8.5891	$355.53
44383	Ileoscopy w/stent	Y		A2	28.3019	$1,171.50
44385	Endoscopy of bowel pouch	Y		A2	8.3045	$343.75
44386	Endoscopy, bowel pouch/biop	Y		A2	8.3045	$343.75
44388	Colonoscopy	Y		A2	8.3045	$343.75
44389	Colonoscopy with biopsy	Y		A2	8.3045	$343.75
44390	Colonoscopy for foreign body	Y		A2	8.3045	$343.75
44391	Colonoscopy for bleeding	Y		A2	8.3045	$343.75
44392	Colonoscopy & polypectomy	Y		A2	8.3045	$343.75
44393	Colonoscopy, lesion removal	Y		A2	8.3045	$343.75
44394	Colonoscopy w/snare	Y		A2	8.3045	$343.75
44397	Colonoscopy w/stent	Y		A2	16.4525	$681.02
44500	Intro, gastrointestinal tube	Y		G2	4.4814	$185.50
44701	Intraop colon lavage add-on	N		N1		
45000	Drainage of pelvic abscess	Y		A2	9.6306	$398.64
45005	Drainage of rectal abscess	Y		A2	11.2082	$463.94
45020	Drainage of rectal abscess	Y		A2	11.2082	$463.94
45100	Biopsy of rectum	Y		A2	15.2275	$630.31
45108	Removal of anorectal lesion	Y		A2	16.5584	$685.40
45150	Excision of rectal stricture	Y		A2	16.5584	$685.40

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45160	Excision of rectal lesion	Y		A2	16.5584	$685.40
45170	Excision of rectal lesion	Y		A2	16.5584	$685.40
45190	Destruction, rectal tumor	Y		A2	27.0766	$1,120.78
45300	Proctosigmoidoscopy dx	Y		P3	1.6032	$66.36
45303	Proctosigmoidoscopy dilate	Y		P2	8.9051	$368.61
45305	Proctosigmoidoscopy w/bx	Y		A2	8.3748	$346.66
45307	Proctosigmoidoscopy fb	Y		A2	15.4688	$640.30
45308	Proctosigmoidoscopy removal	Y		A2	8.3748	$346.66
45309	Proctosigmoidoscopy removal	Y		A2	8.3748	$346.66
45315	Proctosigmoidoscopy removal	Y		A2	8.3748	$346.66
45317	Proctosigmoidoscopy bleed	Y		A2	8.3748	$346.66
45320	Proctosigmoidoscopy ablate	Y		A2	15.4688	$640.30
45321	Proctosigmoidoscopy volvul	Y		A2	15.4688	$640.30
45327	Proctosigmoidoscopy w/stent	Y		A2	16.4525	$681.02
45330	Diagnostic sigmoidoscopy	Y		P3	2.1173	$87.64
45331	Sigmoidoscopy and biopsy	Y		A2	6.2612	$259.17
45332	Sigmoidoscopy w/fb removal	Y		A2	6.2612	$259.17
45333	Sigmoidoscopy & polypectomy	Y		A2	8.3748	$346.66
45334	Sigmoidoscopy for bleeding	Y		A2	8.3748	$346.66
45335	Sigmoidoscopy w/submuc inj	Y		A2	6.2612	$259.17
45337	Sigmoidoscopy & decompress	Y		A2	6.2612	$259.17
45338	Sigmoidoscopy w/tumr remove	Y		A2	8.3748	$346.66
45339	Sigmoidoscopy w/ablate tumr	Y		A2	8.3748	$346.66
45340	Sig w/balloon dilation	Y		A2	8.3748	$346.66
45341	Sigmoidoscopy w/ultrasound	Y		A2	8.3748	$346.66
45342	Sigmoidoscopy w/us guide bx	Y		A2	8.3748	$346.66
45345	Sigmoidoscopy w/stent	Y		A2	16.4525	$681.02
45355	Surgical colonoscopy	Y		A2	8.3045	$343.75
45378	Diagnostic colonoscopy	Y		A2	9.6357	$398.85
45379	Colonoscopy w/fb removal	Y		A2	9.6357	$398.85
45380	Colonoscopy and biopsy	Y		A2	9.6357	$398.85
45381	Colonoscopy, submucous inj	Y		A2	9.6357	$398.85
45382	Colonoscopy/control bleeding	Y		A2	9.6357	$398.85
45383	Lesion removal colonoscopy	Y		A2	9.6357	$398.85
45384	Lesion remove colonoscopy	Y		A2	9.6357	$398.85
45385	Lesion removal colonoscopy	Y		A2	9.6357	$398.85
45386	Colonoscopy dilate stricture	Y		A2	9.6357	$398.85
45387	Colonoscopy w/stent	Y		A2	16.4525	$681.02

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45391	Colonoscopy w/endoscope us	Y		A2	9.6357	$398.85
45392	Colonoscopy w/endoscopic fnb	Y		A2	9.6357	$398.85
45500	Repair of rectum	Y		A2	16.5584	$685.40
45505	Repair of rectum	Y		A2	20.3868	$843.87
45520	Treatment of rectal prolapse	Y		P2	0.8075	$33.42
45560	Repair of rectocele	Y		A2	20.3868	$843.87
45900	Reduction of rectal prolapse	Y		A2	6.5289	$270.25
45905	Dilation of anal sphincter	Y		A2	15.2275	$630.31
45910	Dilation of rectal narrowing	Y		A2	15.2275	$630.31
45915	Remove rectal obstruction	Y		A2	9.6306	$398.64
45990	Surg dx exam, anorectal	Y		A2	14.9808	$620.10
46020	Placement of seton	Y		A2	17.3123	$716.61
46030	Removal of rectal marker	Y		A2	6.5289	$270.25
46040	Incision of rectal abscess	Y		A2	17.3123	$716.61
46045	Incision of rectal abscess	Y		A2	16.5584	$685.40
46050	Incision of anal abscess	Y		A2	9.6306	$398.64
46060	Incision of rectal abscess	Y		A2	16.5584	$685.40
46070	Incision of anal septum	Y		G2	11.9098	$492.98
46080	Incision of anal sphincter	Y		A2	17.3123	$716.61
46083	Incise external hemorrhoid	Y		P2	1.8231	$75.46
46200	Removal of anal fissure	Y		A2	16.5584	$685.40
46210	Removal of anal crypt	Y		A2	16.5584	$685.40
46211	Removal of anal crypts	Y		A2	16.5584	$685.40
46220	Removal of anal tag	Y		A2	15.2275	$630.31
46221	Ligation of hemorrhoid(s)	Y		P3	2.9974	$124.07
46230	Removal of anal tags	Y		A2	15.2275	$630.31
46250	Hemorrhoidectomy	Y		A2	17.3123	$716.61
46255	Hemorrhoidectomy	Y		A2	17.3123	$716.61
46257	Remove hemorrhoids & fissure	Y		A2	17.3123	$716.61
46258	Remove hemorrhoids & fistula	Y		A2	17.3123	$716.61
46260	Hemorrhoidectomy	Y		A2	17.3123	$716.61
46261	Remove hemorrhoids & fissure	Y		A2	18.7256	$775.11
46262	Remove hemorrhoids & fistula	Y		A2	18.7256	$775.11
46270	Removal of anal fistula	Y		A2	17.3123	$716.61
46275	Removal of anal fistula	Y		A2	17.3123	$716.61
46280	Removal of anal fistula	Y		A2	18.7256	$775.11
46285	Removal of anal fistula	Y		A2	15.2275	$630.31
46288	Repair anal fistula	Y		A2	18.7256	$775.11

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46320	Removal of hemorrhoid clot	Y		P3	2.0303	$84.04
46500	Injection into hemorrhoid(s)	Y		P3	2.7968	$115.77
46505	Chemodenervation anal musc	Y		G2	11.9098	$492.98
46600	Diagnostic anoscopy	N		P2	0.6301	$26.08
46604	Anoscopy and dilation	Y		P2	8.9051	$368.61
46606	Anoscopy and biopsy	Y		P3	3.346	$138.50
46608	Anoscopy, remove for body	Y		A2	8.3748	$346.66
46610	Anoscopy, remove lesion	Y		A2	15.4688	$640.30
46611	Anoscopy	Y		A2	8.3748	$346.66
46612	Anoscopy, remove lesions	Y		A2	15.4688	$640.30
46614	Anoscopy, control bleeding	Y		P3	1.76	$72.85
46615	Anoscopy	Y		A2	16.7997	$695.39
46700	Repair of anal stricture	Y		A2	17.3123	$716.61
46706	Repr of anal fistula w/glue	Y		A2	19.0556	$788.77
46750	Repair of anal sphincter	Y		A2	21.1405	$875.07
46753	Reconstruction of anus	Y		A2	17.3123	$716.61
46754	Removal of suture from anus	Y		A2	16.5584	$685.40
46760	Repair of anal sphincter	Y		A2	20.3868	$843.87
46761	Repair of anal sphincter	Y		A2	21.1405	$875.07
46762	Implant artificial sphincter	Y		A2	26.8531	$1,111.53
46900	Destruction, anal lesion(s)	Y		P2	2.6609	$110.14
46910	Destruction, anal lesion(s)	Y		P3	3.1802	$131.64
46916	Cryosurgery, anal lesion(s)	Y		P2	1.4792	$61.23
46917	Laser surgery, anal lesions	Y		A2	13.799	$571.18
46922	Excision of anal lesion(s)	Y		A2	13.799	$571.18
46924	Destruction, anal lesion(s)	Y		A2	13.799	$571.18
46930*	Destroy internal hemorrhoids	Y	NI	P3	3.0846	$127.68
46934	Destruction of hemorrhoids	N	CH	D5		
46935	Destruction of hemorrhoids	N	CH	D5		
46936	Destruction of hemorrhoids	N	CH	D5		
46937	Cryotherapy of rectal lesion	Y		A2	16.5584	$685.40
46938	Cryotherapy of rectal lesion	Y		A2	20.3868	$843.87
46940	Treatment of anal fissure	Y		P3	2.2828	$94.49
46942	Treatment of anal fissure	Y		P3	2.2219	$91.97
46945	Ligation of hemorrhoids	Y		P3	3.7816	$156.53
46946	Ligation of hemorrhoids	Y		A2	9.877	$408.84
46947	Hemorrhoidopexy by stapling	Y		A2	26.8531	$1,111.53
47000	Needle biopsy of liver	Y		A2	8.5923	$355.66

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HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
47001	Needle biopsy, liver add-on	N		N1		
47382	Percut ablate liver rf	Y		G2	45.3434	$1,876.90
47500	Injection for liver x-rays	N		N1		
47505	Injection for liver x-rays	N		N1		
47510	Insert catheter, bile duct	Y		A2	20.0807	$831.20
47511	Insert bile duct drain	Y		A2	29.5016	$1,221.16
47525	Change bile duct catheter	Y		A2	11.5278	$477.17
47530	Revise/reinsert bile tube	Y		A2	11.5278	$477.17
47552	Biliary endoscopy thru skin	Y		A2	20.0807	$831.20
47553	Biliary endoscopy thru skin	Y		A2	20.8344	$862.40
47554	Biliary endoscopy thru skin	Y		A2	20.8344	$862.40
47555	Biliary endoscopy thru skin	Y		A2	20.8344	$862.40
47556	Biliary endoscopy thru skin	Y		A2	29.5016	$1,221.16
47560	Laparoscopy w/cholangio	Y		A2	24.4797	$1,013.29
47561	Laparo w/cholangio/biopsy	Y		A2	24.4797	$1,013.29
47562	Laparoscopic cholecystectomy	Y		G2	45.1703	$1,869.73
47563	Laparo cholecystectomy/graph	Y		G2	45.1703	$1,869.73
47564	Laparo cholecystectomy/explr	Y		G2	45.1703	$1,869.73
47630	Remove bile duct stone	Y		A2	20.8344	$862.40
48102	Needle biopsy, pancreas	Y		A2	8.5923	$355.66
49080	Puncture, peritoneal cavity	Y		A2	5.2248	$216.27
49081	Removal of abdominal fluid	Y		A2	5.2248	$216.27
49180	Biopsy, abdominal mass	Y		A2	8.5923	$355.66
49250	Excision of umbilicus	Y		A2	18.8346	$779.62
49320	Diag laparo separate proc	Y		A2	24.4797	$1,013.29
49321	Laparoscopy, biopsy	Y		A2	25.8933	$1,071.80
49322	Laparoscopy, aspiration	Y		A2	25.8933	$1,071.80
49324	Lap insertion perm ip cath	Y	CH	G2	36.9453	$1,529.28
49325	Lap revision perm ip cath	Y	CH	G2	36.9453	$1,529.28
49326	Lap w/omentopexy add-on	Y	CH	G2	36.9453	$1,529.28
49400	Air injection into abdomen	N		N1		
49402	Remove foreign body, adbomen	Y		A2	16.6673	$689.91
49419	Insrt abdom cath for chemotx	Y		A2	19.9947	$827.64
49420	Insert abdom drain, temp	Y		A2	18.4838	$765.10
49421	Insert abdom drain, perm	Y		A2	18.4838	$765.10
49422	Remove perm cannula/catheter	Y		A2	14.7102	$608.90
49423	Exchange drainage catheter	Y		G2	15.211	$629.63
49424	Assess cyst, contrast inject	N		N1		

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49426	Revise abdomen-venous shunt	Y		A2	16.6673	$689.91
49427	Injection, abdominal shunt	N		N1		
49429	Removal of shunt	Y		G2	21.5762	$893.10
49440	Place gastrostomy tube perc	Y		G2	8.4372	$349.24
49441	Place duod/jej tube perc	Y		G2	8.4372	$349.24
49446	Change g-tube to g-j perc	Y		G2	8.4372	$349.24
49450	Replace g/c tube perc	Y		G2	4.4814	$185.50
49451	Replace duod/jej tube perc	Y		G2	4.4814	$185.50
49452	Replace g-j tube perc	Y		G2	4.4814	$185.50
49460	Fix g/colon tube w/device	Y		G2	4.4814	$185.50
49465	Fluoro exam of g/colon tube	N		N1		
49495	Rpr ing hernia baby, reduc	Y		A2	22.8577	$946.15
49496	Rpr ing hernia baby, blocked	Y		A2	22.8577	$946.15
49500	Rpr ing hernia, init, reduce	Y		A2	22.8577	$946.15
49501	Rpr ing hernia, init blocked	Y		A2	31.2087	$1,291.82
49505	Prp i/hern init reduc >5 yr	Y		A2	22.8577	$946.15
49507	Prp i/hern init block >5 yr	Y		A2	31.2087	$1,291.82
49520	Rerepair ing hernia, reduce	Y		A2	27.157	$1,124.11
49521	Rerepair ing hernia, blocked	Y		A2	31.2087	$1,291.82
49525	Repair ing hernia, sliding	Y		A2	22.8577	$946.15
49540	Repair lumbar hernia	Y		A2	20.6905	$856.44
49550	Rpr rem hernia, init, reduce	Y		A2	23.8825	$988.57
49553	Rpr fem hernia, init blocked	Y		A2	31.2087	$1,291.82
49555	Rerepair fem hernia, reduce	Y		A2	23.8825	$988.57
49557	Rerepair fem hernia, blocked	Y		A2	31.2087	$1,291.82
49560	Rpr ventral hern init, reduc	Y		A2	22.8577	$946.15
49561	Rpr ventral hern init, block	Y		A2	31.2087	$1,291.82
49565	Rerepair ventrl hern, reduce	Y		A2	22.8577	$946.15
49566	Rerepair ventrl hern, block	Y		A2	31.2087	$1,291.82
49568	Hernia repair w/mesh	Y		A2	27.157	$1,124.11
49570	Rpr epigastric hern, reduce	Y		A2	22.8577	$946.15
49572	Rpr epigastric hern, blocked	Y		A2	31.2087	$1,291.82
49580	Rpr umbil hern, reduc < 5 yr	Y		A2	22.8577	$946.15
49582	Rpr umbil hern, block < 5 yr	Y		A2	31.2087	$1,291.82
49585	Rpr umbil hern, reduc > 5 yr	Y		A2	22.8577	$946.15
49587	Rpr umbil hern, block > 5 yr	Y		A2	31.2087	$1,291.82
49590	Repair spigelian hernia	Y		A2	21.4444	$887.65
49600	Repair umbilical lesion	Y		A2	22.8577	$946.15

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49650	Lap ing hernia repair init	Y		A2	30.0056	$1,242.02
49651	Lap ing hernia repair recur	Y		A2	34.3048	$1,419.98
49652	Lap vent/abd hernia repair	Y	NI	G2	36.9453	$1,529.28
49653	Lap vent/abd hern proc comp	Y	NI	G2	36.9453	$1,529.28
49654	Lap inc hernia repair	Y	NI	G2	36.9453	$1,529.28
49655	Lap inc hern repair comp	Y	NI	G2	36.9453	$1,529.28
49656	Lap inc hernia repair recur	Y	NI	G2	36.9453	$1,529.28
49657	Lap inc hern recur comp	Y	NI	G2	36.9453	$1,529.28
50200	Biopsy of kidney	Y		A2	8.5923	$355.66
50382	Change ureter stent, percut	Y		G2	24.95	$1,032.76
50384	Remove ureter stent, percut	Y		G2	18.3252	$758.54
50385	Change stent via transureth	Y		G2	18.3252	$758.54
50386	Remove stent via transureth	Y		G2	7.0309	$291.03
50387	Change ext/int ureter stent	Y		G2	15.211	$629.63
50389	Remove renal tube w/fluoro	Y		G2	7.0309	$291.03
50390	Drainage of kidney lesion	Y		A2	8.5923	$355.66
50391	Instll rx agnt into rnal tub	Y		P2	1.0175	$42.12
50392	Insert kidney drain	Y		A2	13.0848	$541.62
50393	Insert ureteral tube	Y		A2	16.3972	$678.73
50394	Injection for kidney x-ray	N		N1		
50395	Create passage to kidney	Y		A2	13.0848	$541.62
50396	Measure kidney pressure	Y		A2	2.4603	$101.84
50398	Change kidney tube	Y		A2	11.5278	$477.17
50551	Kidney endoscopy	Y		A2	7.4377	$307.87
50553	Kidney endoscopy	Y		A2	16.3972	$678.73
50555	Kidney endoscopy & biopsy	Y		A2	7.4377	$307.87
50557	Kidney endoscopy & treatment	Y		A2	16.3972	$678.73
50561	Kidney endoscopy & treatment	Y		A2	16.3972	$678.73
50562	Renal scope w/tumor resect	Y		G2	7.0309	$291.03
50570	Kidney endoscopy	Y		G2	7.0309	$291.03
50572	Kidney endoscopy	Y		G2	7.0309	$291.03
50574	Kidney endoscopy & biopsy	Y		G2	7.0309	$291.03
50575	Kidney endoscopy	Y		G2	34.9731	$1,447.64
50576	Kidney endoscopy & treatment	Y		G2	18.3252	$758.54
50580	Kidney endoscopy & treatment	Y		G2	18.3252	$758.54
50590	Fragmenting of kidney stone	Y		G2	40.8566	$1,691.18
50592	Perc rf ablate renal tumor	Y		G2	45.3434	$1,876.90
50684	Injection for ureter x-ray	N		N1		

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50686	Measure ureter pressure	Y	CH	R2	1.0175	$42.12
50688	Change of ureter tube/stent	Y		A2	11.5278	$477.17
50690	Injection for ureter x-ray	N		N1		
50947	Laparo new ureter/bladder	Y		A2	38.3565	$1,587.69
50948	Laparo new ureter/bladder	Y		A2	38.3565	$1,587.69
50951	Endoscopy of ureter	Y		A2	7.4377	$307.87
50953	Endoscopy of ureter	Y		A2	7.4377	$307.87
50955	Ureter endoscopy & biopsy	Y		A2	16.3972	$678.73
50957	Ureter endoscopy & treatment	Y		A2	16.3972	$678.73
50961	Ureter endoscopy & treatment	Y		A2	16.3972	$678.73
50970	Ureter endoscopy	Y		A2	7.4377	$307.87
50972	Ureter endoscopy & catheter	Y		A2	7.4377	$307.87
50974	Ureter endoscopy & biopsy	Y		A2	13.0848	$541.62
50976	Ureter endoscopy & treatment	Y		A2	13.0848	$541.62
50980	Ureter endoscopy & treatment	Y		A2	16.3972	$678.73
51020	Incise & treat bladder	Y		A2	19.8956	$823.54
51030	Incise & treat bladder	Y		A2	19.8956	$823.54
51040	Incise & drain bladder	Y		A2	19.8956	$823.54
51045	Incise bladder/drain ureter	Y		A2	8.2178	$340.16
51050	Removal of bladder stone	Y		A2	19.8956	$823.54
51065	Remove ureter calculus	Y		A2	19.8956	$823.54
51080	Drainage of bladder abscess	Y		A2	13.3745	$553.61
51100	Drain bladder by needle	Y		P3	0.7755	$32.10
51101	Drain bladder by trocar/cath	Y		P2	1.0175	$42.12
51102	Drain bl w/cath insertion	Y		A2	13.69	$566.67
51500	Removal of bladder cyst	Y		A2	22.8577	$946.15
51520	Removal of bladder lesion	Y		A2	19.8956	$823.54
51600	Injection for bladder x-ray	N		N1		
51605	Preparation for bladder xray	N		N1		
51610	Injection for bladder x-ray	N		N1		
51700	Irrigation of bladder	Y		P3	1.3244	$54.82
51701	Insert bladder catheter	N		P2	0.6301	$26.08
51702	Insert temp bladder cath	N		P2	0.6301	$26.08
51703	Insert bladder cath, complex	Y		P2	1.0175	$42.12
51705	Change of bladder tube	Y	CH	P2	1.8231	$75.46
51710	Change of bladder tube	Y		A2	11.5278	$477.17
51715	Endoscopic injection/implant	Y		A2	20.9311	$866.40
51720	Treatment of bladder lesion	Y		P3	1.4638	$60.59

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51725	Simple cystometrogram	Y		P2	2.812	$116.40
51726	Complex cystometrogram	Y		A2	3.8734	$160.33
51736	Urine flow measurement	Y		P3	0.5315	$22.00
51741	Electro-uroflowmetry, first	Y		P3	0.6187	$25.61
51772	Urethra pressure profile	Y		A2	2.4603	$101.84
51784	Anal/urinary muscle study	Y		P2	1.0175	$42.12
51785	Anal/urinary muscle study	Y		A2	1.6998	$70.36
51792	Urinary reflex study	Y		P2	1.0175	$42.12
51795	Urine voiding pressure study	Y		P2	1.8231	$75.46
51797	Intraabdominal pressure test	Y		P2	1.8231	$75.46
51798	Us urine capacity measure	N		P3	0.453	$18.75
51880	Repair of bladder opening	Y		A2	16.3972	$678.73
51992	Laparo sling operation	Y		A2	31.0304	$1,284.44
52000	Cystoscopy	Y		A2	7.4377	$307.87
52001	Cystoscopy, removal of clots	Y		A2	13.8649	$573.91
52005	Cystoscopy & ureter catheter	Y		A2	14.4157	$596.71
52007	Cystoscopy and biopsy	Y		A2	17.7284	$733.83
52010	Cystoscopy & duct catheter	Y		A2	8.2178	$340.16
52204	Cystoscopy w/biopsy(s)	Y		A2	14.4157	$596.71
52214	Cystoscopy and treatment	Y		A2	17.7284	$733.83
52224	Cystoscopy and treatment	Y		A2	17.7284	$733.83
52234	Cystoscopy and treatment	Y		A2	17.7284	$733.83
52235	Cystoscopy and treatment	Y		A2	18.4821	$765.03
52240	Cystoscopy and treatment	Y		A2	18.4821	$765.03
52250	Cystoscopy and radiotracer	Y		A2	19.8956	$823.54
52260	Cystoscopy and treatment	Y		A2	14.4157	$596.71
52265	Cystoscopy and treatment	Y		P2	7.0309	$291.03
52270	Cystoscopy & revise urethra	Y		A2	14.4157	$596.71
52275	Cystoscopy & revise urethra	Y		A2	17.7284	$733.83
52276	Cystoscopy and treatment	Y		A2	18.4821	$765.03
52277	Cystoscopy and treatment	Y		A2	17.7284	$733.83
52281	Cystoscopy and treatment	Y		A2	14.4157	$596.71
52282	Cystoscopy, implant stent	Y		A2	33.258	$1,376.65
52283	Cystoscopy and treatment	Y		A2	17.7284	$733.83
52285	Cystoscopy and treatment	Y		A2	14.4157	$596.71
52290	Cystoscopy and treatment	Y		A2	14.4157	$596.71
52300	Cystoscopy and treatment	Y		A2	17.7284	$733.83
52301	Cystoscopy and treatment	Y		A2	18.4821	$765.03

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52305	Cystoscopy and treatment	Y		A2	17.7284	$733.83
52310	Cystoscopy and treatment	Y		A2	13.8649	$573.91
52315	Cystoscopy and treatment	Y		A2	17.7284	$733.83
52317	Remove bladder stone	Y		A2	16.3972	$678.73
52318	Remove bladder stone	Y		A2	17.7284	$733.83
52320	Cystoscopy and treatment	Y		A2	20.9202	$865.95
52325	Cystoscopy, stone removal	Y		A2	19.8956	$823.54
52327	Cystoscopy, inject material	Y		A2	22.7398	$941.27
52330	Cystoscopy and treatment	Y		A2	17.7284	$733.83
52332	Cystoscopy and treatment	Y		A2	17.7284	$733.83
52334	Create passage to kidney	Y		A2	18.4821	$765.03
52341	Cysto w/ureter stricture tx	Y		A2	18.4821	$765.03
52342	Cysto w/up stricture tx	Y		A2	18.4821	$765.03
52343	Cysto w/renal stricture tx	Y		A2	18.4821	$765.03
52344	Cysto/uretero, stricture tx	Y		A2	18.4821	$765.03
52345	Cysto/uretero w/up stricture	Y		A2	18.4821	$765.03
52346	Cystouretero w/renal strict	Y		A2	18.4821	$765.03
52351	Cystouretero & or pyeloscope	Y		A2	18.4821	$765.03
52352	Cystouretero w/stone remove	Y		A2	19.8956	$823.54
52353	Cystouretero w/lithotripsy	Y		A2	24.9071	$1,030.98
52354	Cystouretero w/biopsy	Y		A2	19.8956	$823.54
52355	Cystouretero w/excise tumor	Y		A2	19.8956	$823.54
52400	Cystouretero w/congen repr	Y		A2	18.4821	$765.03
52402	Cystourethro cut ejacul duct	Y		A2	18.4821	$765.03
52450	Incision of prostate	Y		A2	18.4821	$765.03
52500	Revision of bladder neck	Y		A2	18.4821	$765.03
52601	Prostatectomy (turp)	Y		A2	24.9071	$1,030.98
52606	Control postop bleeding	N	CH	D5		
52612	Prostatectomy, first stage	N	CH	D5		
52614	Prostatectomy, second stage	N	CH	D5		
52620	Remove residual prostate	N	CH	D5		
52630	Remove prostate regrowth	Y		A2	22.7398	$941.27
52640	Relieve bladder contracture	Y		A2	17.7284	$733.83
52647	Laser surgery of prostate	Y		A2	38.1055	$1,577.30
52648	Laser surgery of prostate	Y		A2	38.1055	$1,577.30
52700	Drainage of prostate abscess	Y		A2	17.7284	$733.83
53000	Incision of urethra	Y		A2	13.6064	$563.21
53010	Incision of urethra	Y		A2	13.6064	$563.21

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HCPCS Code	Short Descriptor	Subject to Multiple Procedure Discounting	Comment Indicator	Payment Indicator	CY 2009 Second Year Transition Payment Weight	CY 2009 Second Year Transition Payment
53020	Incision of urethra	Y		A2	13.6064	$563.21
53025	Incision of urethra	Y		R2	19.3683	$801.71
53040	Drainage of urethra abscess	Y		A2	14.9375	$618.31
53060	Drainage of urethra abscess	Y		P3	1.7689	$73.22
53080	Drainage of urinary leakage	Y		A2	15.6913	$649.51
53085	Drainage of urinary leakage	Y		G2	19.3683	$801.71
53200	Biopsy of urethra	Y		A2	13.6064	$563.21
53210	Removal of urethra	Y		A2	23.3692	$967.32
53215	Removal of urethra	Y		A2	18.1294	$750.43
53220	Treatment of urethra lesion	Y		A2	20.1771	$835.19
53230	Removal of urethra lesion	Y		A2	20.1771	$835.19
53235	Removal of urethra lesion	Y		A2	15.6913	$649.51
53240	Surgery for urethra pouch	Y		A2	20.1771	$835.19
53250	Removal of urethra gland	Y		A2	14.9375	$618.31
53260	Treatment of urethra lesion	Y		A2	14.9375	$618.31
53265	Treatment of urethra lesion	Y		A2	14.9375	$618.31
53270	Removal of urethra gland	Y		A2	14.9375	$618.31
53275	Repair of urethra defect	Y		A2	14.9375	$618.31
53400	Revise urethra, stage 1	Y		A2	20.9311	$866.40
53405	Revise urethra, stage 2	Y		A2	20.1771	$835.19
53410	Reconstruction of urethra	Y		A2	20.1771	$835.19
53420	Reconstruct urethra, stage 1	Y		A2	20.9311	$866.40
53425	Reconstruct urethra, stage 2	Y		A2	20.1771	$835.19
53430	Reconstruction of urethra	Y		A2	20.1771	$835.19
53431	Reconstruct urethra/bladder	Y		A2	20.1771	$835.19
53440	Male sling procedure	N		H8	116.2281	$4,811.03
53442	Remove/revise male sling	Y		A2	18.8462	$780.10
53444	Insert tandem cuff	N		H8	116.2281	$4,811.03
53445	Insert uro/ves nck sphincter	N		H8	195.2337	$8,081.31
53446	Remove uro sphincter	Y		A2	18.8462	$780.10
53447	Remove/replace ur sphincter	N		H8	195.2337	$8,081.31
53449	Repair uro sphincter	Y		A2	18.8462	$780.10
53450	Revision of urethra	Y		A2	18.8462	$780.10
53460	Revision of urethra	Y		A2	13.6064	$563.21
53502	Repair of urethra injury	Y		A2	14.9375	$618.31
53505	Repair of urethra injury	Y		A2	20.1771	$835.19
53510	Repair of urethra injury	Y		A2	14.9375	$618.31
53515	Repair of urethra injury	Y		A2	20.1771	$835.19

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53520	Repair of urethra defect	Y		A2	20.1771	$835.19
53600	Dilate urethra stricture	Y		P3	1.0195	$42.20
53601	Dilate urethra stricture	Y		P2	1.0175	$42.12
53605	Dilate urethra stricture	Y		A2	14.4157	$596.71
53620	Dilate urethra stricture	Y		P3	1.5684	$64.92
53621	Dilate urethra stricture	Y		P3	1.6469	$68.17
53660	Dilation of urethra	Y		P2	1.0175	$42.12
53661	Dilation of urethra	Y		P2	1.0175	$42.12
53665	Dilation of urethra	Y		A2	13.6064	$563.21
53850	Prostatic microwave thermotx	Y		P2	44.6682	$1,848.95
53852	Prostatic rf thermotx	Y		P2	44.6682	$1,848.95
53853	Prostatic water thermother	N	CH	D5		
54000	Slitting of prepuce	Y		A2	14.9375	$618.31
54001	Slitting of prepuce	Y		A2	14.9375	$618.31
54015	Drain penis lesion	Y		A2	16.8729	$698.42
54050	Destruction, penis lesion(s)	Y		P2	0.8075	$33.42
54055	Destruction, penis lesion(s)	Y		P3	1.6469	$68.17
54056	Cryosurgery, penis lesion(s)	Y		P2	0.8075	$33.42
54057	Laser surg, penis lesion(s)	Y		A2	13.799	$571.18
54060	Excision of penis lesion(s)	Y		A2	13.799	$571.18
54065	Destruction, penis lesion(s)	Y		A2	13.799	$571.18
54100	Biopsy of penis	Y		A2	11.673	$483.18
54105	Biopsy of penis	Y		A2	14.5718	$603.17
54110	Treatment of penis lesion	Y		A2	22.5925	$935.17
54111	Treat penis lesion, graft	Y		A2	22.5925	$935.17
54112	Treat penis lesion, graft	Y		A2	22.5925	$935.17
54115	Treatment of penis lesion	Y		A2	13.3745	$553.61
54120	Partial removal of penis	Y		A2	22.5925	$935.17
54150	Circumcision w/regionl block	Y		A2	15.0567	$623.24
54160	Circumcision, neonate	Y		A2	16.3878	$678.34
54161	Circum 28 days or older	Y		A2	16.3878	$678.34
54162	Lysis penil circumic lesion	Y		A2	16.3878	$678.34
54163	Repair of circumcision	Y		A2	16.3878	$678.34
54164	Frenulotomy of penis	Y		A2	16.3878	$678.34
54200	Treatment of penis lesion	Y		P3	1.7165	$71.05
54205	Treatment of penis lesion	Y		A2	24.7597	$1,024.88
54220	Treatment of penis lesion	Y		A2	2.4603	$101.84
54230	Prepare penis study	N		N1		

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54231	Dynamic cavernosometry	Y		P3	1.6119	$66.72
54235	Penile injection	Y		P3	1.1415	$47.25
54240	Penis study	Y		P3	0.8103	$33.54
54250	Penis study	Y		P3	0.2875	$11.90
54300	Revision of penis	Y		A2	23.3462	$966.37
54304	Revision of penis	Y		A2	23.3462	$966.37
54308	Reconstruction of urethra	Y		A2	23.3462	$966.37
54312	Reconstruction of urethra	Y		A2	23.3462	$966.37
54316	Reconstruction of urethra	Y		A2	23.3462	$966.37
54318	Reconstruction of urethra	Y		A2	23.3462	$966.37
54322	Reconstruction of urethra	Y		A2	23.3462	$966.37
54324	Reconstruction of urethra	Y		A2	23.3462	$966.37
54326	Reconstruction of urethra	Y		A2	23.3462	$966.37
54328	Revise penis/urethra	Y		A2	23.3462	$966.37
54340	Secondary urethral surgery	Y		A2	23.3462	$966.37
54344	Secondary urethral surgery	Y		A2	23.3462	$966.37
54348	Secondary urethral surgery	Y		A2	23.3462	$966.37
54352	Reconstruct urethra/penis	Y		A2	23.3462	$966.37
54360	Penis plastic surgery	Y		A2	23.3462	$966.37
54380	Repair penis	Y		A2	23.3462	$966.37
54385	Repair penis	Y		A2	23.3462	$966.37
54400	Insert semi-rigid prosthesis	N		H8	116.9821	$4,842.24
54401	Insert self-contd prosthesis	N		H8	197.3186	$8,167.61
54405	Insert multi-comp penis pros	N		H8	197.3186	$8,167.61
54406	Remove muti-comp penis pros	Y		A2	23.3462	$966.37
54408	Repair multi-comp penis pros	Y		A2	23.3462	$966.37
54410	Remove/replace penis prosth	N		H8	197.3186	$8,167.61
54415	Remove self-contd penis pros	Y		A2	23.3462	$966.37
54416	Remv/repl penis contain pros	N		H8	197.3186	$8,167.61
54420	Revision of penis	Y		A2	24.7597	$1,024.88
54435	Revision of penis	Y		A2	24.7597	$1,024.88
54440	Repair of penis	Y		A2	24.7597	$1,024.88
54450	Preputial stretching	Y		A2	3.8734	$160.33
54500	Biopsy of testis	Y		A2	10.5126	$435.15
54505	Biopsy of testis	Y		A2	15.0567	$623.24
54512	Excise lesion testis	Y		A2	16.3878	$678.34
54520	Removal of testis	Y		A2	17.1415	$709.54
54522	Orchiectomy, partial	Y		A2	17.1415	$709.54

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54530	Removal of testis	Y		A2	22.8577	$946.15
54550	Exploration for testis	Y		A2	22.8577	$946.15
54560	Exploration for testis	Y		G2	22.2689	$921.78
54600	Reduce testis torsion	Y		A2	18.5551	$768.05
54620	Suspension of testis	Y		A2	17.1415	$709.54
54640	Suspension of testis	Y		A2	22.8577	$946.15
54660	Revision of testis	Y		A2	16.3878	$678.34
54670	Repair testis injury	Y		A2	17.1415	$709.54
54680	Relocation of testis(es)	Y		A2	17.1415	$709.54
54690	Laparoscopy, orchiectomy	Y		A2	38.3565	$1,587.69
54692	Laparoscopy, orchiopexy	Y		G2	68.1823	$2,822.27
54700	Drainage of scrotum	Y		A2	16.3878	$678.34
54800	Biopsy of epididymis	Y		A2	3.6784	$152.26
54830	Remove epididymis lesion	Y		A2	17.1415	$709.54
54840	Remove epididymis lesion	Y		A2	18.5551	$768.05
54860	Removal of epididymis	Y		A2	17.1415	$709.54
54861	Removal of epididymis	Y		A2	18.5551	$768.05
54865	Explore epididymis	Y		A2	15.0567	$623.24
54900	Fusion of spermatic ducts	Y		A2	18.5551	$768.05
54901	Fusion of spermatic ducts	Y		A2	18.5551	$768.05
55000	Drainage of hydrocele	Y		P3	1.673	$69.25
55040	Removal of hydrocele	Y		A2	21.4444	$887.65
55041	Removal of hydroceles	Y		A2	23.8825	$988.57
55060	Repair of hydrocele	Y		A2	18.5551	$768.05
55100	Drainage of scrotum abscess	Y		A2	10.0631	$416.54
55110	Explore scrotum	Y		A2	16.3878	$678.34
55120	Removal of scrotum lesion	Y		A2	16.3878	$678.34
55150	Removal of scrotum	Y		A2	15.0567	$623.24
55175	Revision of scrotum	Y		A2	15.0567	$623.24
55180	Revision of scrotum	Y		A2	16.3878	$678.34
55200	Incision of sperm duct	Y		A2	16.3878	$678.34
55250	Removal of sperm duct(s)	Y		A2	16.3878	$678.34
55300	Prepare, sperm duct x-ray	N		N1		
55400	Repair of sperm duct	Y		A2	15.0567	$623.24
55450	Ligation of sperm duct	Y		P3	5.3847	$222.89
55500	Removal of hydrocele	Y		A2	17.1415	$709.54
55520	Removal of sperm cord lesion	Y		A2	18.5551	$768.05
55530	Revise spermatic cord veins	Y		A2	18.5551	$768.05

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55535	Revise spermatic cord veins	Y		A2	22.8577	$946.15
55540	Revise hernia & sperm veins	Y		A2	23.8825	$988.57
55550	Laparo ligate spermatic vein	Y		A2	38.3565	$1,587.69
55600	Incise sperm duct pouch	Y		R2	22.2689	$921.78
55680	Remove sperm pouch lesion	Y		A2	15.0567	$623.24
55700	Biopsy of prostate	Y		A2	9.7033	$401.65
55705	Biopsy of prostate	Y		A2	9.7033	$401.65
55706	Prostate saturation sampling	Y	NI	G2	11.2602	$466.09
55720	Drainage of prostate abscess	Y		A2	16.3972	$678.73
55725	Drainage of prostate abscess	Y		A2	17.7284	$733.83
55860	Surgical exposure, prostate	Y		G2	19.5357	$808.64
55870	Electroejaculation	Y		P3	1.9866	$82.23
55873	Cryoablate prostate	Y		H8	154.5737	$6,398.27
55875	Transperi needle place, pros	N		A2	33.258	$1,376.65
55876*	Place rt device/marker, pros	N		P3	1.8211	$75.38
55920	Place needles pelvic for rt	Y		G2	22.8284	$944.94
56405	I & d of vulva/perineum	Y		P3	1.063	$44.00
56420	Drainage of gland abscess	Y		P2	1.3875	$57.43
56440	Surgery for vulva lesion	Y		A2	14.8989	$616.71
56441	Lysis of labial lesion(s)	Y		A2	13.5678	$561.61
56442	Hymenotomy	Y		A2	13.5678	$561.61
56501	Destroy, vulva lesions, sim	Y		P3	1.4638	$60.59
56515	Destroy vulva lesion/s compl	Y		A2	15.8838	$657.48
56605	Biopsy of vulva/perineum	Y		P3	0.8451	$34.98
56606	Biopsy of vulva/perineum	Y		P3	0.3486	$14.43
56620	Partial removal of vulva	Y		A2	18.0907	$748.83
56625	Complete removal of vulva	Y		A2	21.3652	$884.37
56700	Partial removal of hymen	Y		A2	13.5678	$561.61
56740	Remove vagina gland lesion	Y		A2	15.6526	$647.91
56800	Repair of vagina	Y		A2	15.6526	$647.91
56805	Repair clitoris	Y		G2	19.2912	$798.52
56810	Repair of perineum	Y		A2	18.0907	$748.83
56820	Exam of vulva w/scope	Y		P3	1.0804	$44.72
56821	Exam/biopsy of vulva w/scope	Y		P2	1.3875	$57.43
57000	Exploration of vagina	Y		A2	13.5678	$561.61
57010	Drainage of pelvic abscess	Y		A2	14.8989	$616.71
57020	Drainage of pelvic fluid	Y		A2	7.8136	$323.43
57022	I & d vaginal hematoma, pp	Y		G2	12.2817	$508.38

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57023	I & d vag hematoma, non-ob	Y		A2	13.3745	$553.61
57061	Destroy vag lesions, simple	Y		P3	1.3505	$55.90
57065	Destroy vag lesions, complex	Y		A2	13.5678	$561.61
57100	Biopsy of vagina	Y		P3	0.8627	$35.71
57105	Biopsy of vagina	Y		A2	14.8989	$616.71
57130	Remove vagina lesion	Y		A2	14.8989	$616.71
57135	Remove vagina lesion	Y		A2	14.8989	$616.71
57150	Treat vagina infection	Y		P3	0.6274	$25.97
57155	Insert uteri tandems/ovoids	Y		A2	7.8136	$323.43
57160	Insert pessary/other device	Y		P3	0.9062	$37.51
57170	Fitting of diaphragm/cap	Y		P2	0.1486	$6.15
57180	Treat vaginal bleeding	Y		A2	2.7908	$115.52
57200	Repair of vagina	Y		A2	13.5678	$561.61
57210	Repair vagina/perineum	Y		A2	14.8989	$616.71
57220	Revision of urethra	Y		A2	27.3225	$1,130.96
57230	Repair of urethral lesion	Y		A2	22.4342	$928.62
57240	Repair bladder & vagina	Y		A2	24.8723	$1,029.54
57250	Repair rectum & vagina	Y		A2	24.8723	$1,029.54
57260	Repair of vagina	Y		A2	24.8723	$1,029.54
57265	Extensive repair of vagina	Y		A2	33.0351	$1,367.42
57267	Insert mesh/pelvic flr addon	Y		A2	28.1468	$1,165.08
57268	Repair of bowel bulge	Y		A2	22.4342	$928.62
57287	Revise/remove sling repair	Y		G2	32.8544	$1,359.94
57288	Repair bladder defect	Y		A2	29.7606	$1,231.88
57289	Repair bladder & vagina	Y		A2	24.8723	$1,029.54
57291	Construction of vagina	Y		A2	24.8723	$1,029.54
57300	Repair rectum-vagina fistula	Y		A2	22.4342	$928.62
57320	Repair bladder-vagina lesion	Y		G2	32.8544	$1,359.94
57400	Dilation of vagina	Y		A2	14.8989	$616.71
57410	Pelvic examination	Y		A2	14.8989	$616.71
57415	Remove vaginal foreign body	Y		A2	14.8989	$616.71
57420	Exam of vagina w/scope	Y		P3	1.1154	$46.17
57421	Exam/biopsy of vag w/scope	Y		P3	1.4551	$60.23
57452	Exam of cervix w/scope	Y		P3	1.0543	$43.64
57454	Bx/curett of cervix w/scope	Y		P3	1.2896	$53.38
57455	Biopsy of cervix w/scope	Y		P3	1.3679	$56.62
57456	Endocerv curettage w/scope	Y		P3	1.3244	$54.82
57460	Bx of cervix w/scope, leep	Y		P3	4.069	$168.43

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57461	Conz of cervix w/scope, leep	Y		P3	4.3217	$178.89
57500	Biopsy of cervix	Y		P3	1.8646	$77.18
57505	Endocervical curettage	Y		P3	1.185	$49.05
57510	Cauterization of cervix	Y		P3	1.2024	$49.77
57511	Cryocautery of cervix	Y		P2	1.3875	$57.43
57513	Laser surgery of cervix	Y		A2	14.8989	$616.71
57520	Conization of cervix	Y		A2	14.8989	$616.71
57522	Conization of cervix	Y		A2	14.8989	$616.71
57530	Removal of cervix	Y		A2	22.4342	$928.62
57550	Removal of residual cervix	Y		A2	22.4342	$928.62
57556	Remove cervix, repair bowel	Y		A2	29.7606	$1,231.88
57558	D&c of cervical stump	Y		A2	15.6526	$647.91
57700	Revision of cervix	Y		A2	13.5678	$561.61
57720	Revision of cervix	Y		A2	15.6526	$647.91
57800	Dilation of cervical canal	Y		P3	0.6361	$26.33
58100	Biopsy of uterus lining	Y		P3	1.0456	$43.28
58110	Bx done w/colposcopy add-on	N		N1		
58120	Dilation and curettage	Y		A2	14.8989	$616.71
58145	Myomectomy vag method	Y		A2	24.8723	$1,029.54
58301	Remove intrauterine device	Y		P3	0.9758	$40.39
58321	Artificial insemination	Y		P3	0.9149	$37.87
58322	Artificial insemination	Y		P3	0.941	$38.95
58323	Sperm washing	Y		P3	0.2179	$9.02
58340	Catheter for hysterography	N		N1		
58345	Reopen fallopian tube	Y		R2	19.2912	$798.52
58346	Insert heyman uteri capsule	Y		A2	14.8989	$616.71
58350	Reopen fallopian tube	Y		A2	22.4342	$928.62
58353	Endometr ablate, thermal	Y		A2	28.1468	$1,165.08
58356	Endometrial cryoablation	Y		P2	42.6309	$1,764.62
58545	Laparoscopic myomectomy	Y		A2	34.2442	$1,417.47
58546	Laparo-myomectomy, complex	Y		A2	38.3565	$1,587.69
58550	Laparo-asst vag hysterectomy	Y		A2	49.8625	$2,063.96
58552	Laparo-vag hyst incl t/o	Y		G2	45.1703	$1,869.73
58555	Hysteroscopy, dx, sep proc	Y		A2	14.6592	$606.79
58558	Hysteroscopy, biopsy	Y		A2	16.7441	$693.09
58559	Hysteroscopy, lysis	Y		A2	15.9904	$661.89
58560	Hysteroscopy, resect septum	Y		A2	23.8748	$988.25
58561	Hysteroscopy, remove myoma	Y		A2	23.8748	$988.25

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58562	Hysteroscopy, remove fb	Y		A2	16.7441	$693.09
58563	Hysteroscopy, ablation	Y		A2	33.639	$1,392.42
58565	Hysteroscopy, sterilization	Y		A2	37.0869	$1,535.14
58600	Division of fallopian tube	Y		G2	32.8544	$1,359.94
58615	Occlude fallopian tube(s)	Y		G2	19.2912	$798.52
58660	Laparoscopy, lysis	Y		A2	31.0304	$1,284.44
58661	Laparoscopy, remove adnexa	Y		A2	31.0304	$1,284.44
58662	Laparoscopy, excise lesions	Y		A2	31.0304	$1,284.44
58670	Laparoscopy, tubal cautery	Y		A2	28.5923	$1,183.52
58671	Laparoscopy, tubal block	Y		A2	28.5923	$1,183.52
58672	Laparoscopy, fimbrioplasty	Y		A2	31.0304	$1,284.44
58673	Laparoscopy, salpingostomy	Y		A2	31.0304	$1,284.44
58800	Drainage of ovarian cyst(s)	Y		A2	15.6526	$647.91
58805	Drainage of ovarian cyst(s)	Y		G2	32.8544	$1,359.94
58820	Drain ovary abscess, open	Y		A2	22.4342	$928.62
58900	Biopsy of ovary(s)	Y		A2	15.6526	$647.91
58970	Retrieval of oocyte	Y		A2	4.3599	$180.47
58974	Transfer of embryo	Y		A2	4.3599	$180.47
58976	Transfer of embryo	Y		A2	4.3599	$180.47
59000	Amniocentesis, diagnostic	Y		P3	1.5945	$66.00
59001	Amniocentesis, therapeutic	Y		R2	5.985	$247.74
59012	Fetal cord puncture,prenatal	Y		G2	2.9265	$121.14
59015	Chorion biopsy	Y		P3	1.2896	$53.38
59020	Fetal contract stress test	Y		P3	0.6796	$28.13
59025	Fetal non-stress test	Y		P3	0.3573	$14.79
59070	Transabdom amnioinfus w/us	Y		G2	2.9265	$121.14
59072	Umbilical cord occlud w/us	Y		G2	2.9265	$121.14
59076	Fetal shunt placement, w/us	Y		G2	2.9265	$121.14
59100	Remove uterus lesion	Y		R2	32.8544	$1,359.94
59150	Treat ectopic pregnancy	Y		G2	45.1703	$1,869.73
59151	Treat ectopic pregnancy	Y		G2	45.1703	$1,869.73
59160	D & c after delivery	Y		A2	15.6526	$647.91
59200	Insert cervical dilator	Y		P3	0.8714	$36.07
59300	Episiotomy or vaginal repair	Y		P3	1.882	$77.90
59320	Revision of cervix	Y		A2	13.5678	$561.61
59412	Antepartum manipulation	Y		G2	19.2912	$798.52
59414	Deliver placenta	Y		G2	19.2912	$798.52
59812	Treatment of miscarriage	Y		A2	18.0907	$748.83

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59820	Care of miscarriage	Y		A2	18.0907	$748.83
59821	Treatment of miscarriage	Y		A2	18.0907	$748.83
59840	Abortion	Y		A2	18.0907	$748.83
59841	Abortion	Y		A2	18.0907	$748.83
59866	Abortion (mpr)	Y		G2	2.9265	$121.14
59870	Evacuate mole of uterus	Y		A2	18.0907	$748.83
59871	Remove cerclage suture	Y		A2	18.0907	$748.83
60000	Drain thyroid/tongue cyst	Y		A2	7.595	$314.38
60100	Biopsy of thyroid	Y		P3	1.1937	$49.41
60200	Remove thyroid lesion	Y		A2	28.2688	$1,170.13
60280	Remove thyroid duct lesion	Y		A2	30.4361	$1,259.84
60281	Remove thyroid duct lesion	Y		A2	30.4361	$1,259.84
60300	Aspir/inj thyroid cyst	Y		P3	1.5684	$64.92
61000	Remove cranial cavity fluid	Y		R2	6.9935	$289.48
61001	Remove cranial cavity fluid	Y		R2	6.9935	$289.48
61020	Remove brain cavity fluid	Y		A2	5.6621	$234.37
61026	Injection into brain canal	Y		A2	5.6621	$234.37
61050	Remove brain canal fluid	Y		A2	5.6621	$234.37
61055	Injection into brain canal	Y		A2	5.6621	$234.37
61070	Brain canal shunt procedure	Y		A2	4.4058	$182.37
61215	Insert brain-fluid device	Y		A2	26.5042	$1,097.09
61330	Decompress eye socket	Y		G2	40.8314	$1,690.13
61334	Explore orbit/remove object	Y		G2	40.8314	$1,690.13
61790	Treat trigeminal nerve	Y		A2	15.032	$622.22
61791	Treat trigeminal tract	Y		A2	11.1521	$461.62
61795	Brain surgery using computer	N		N1		
61880	Revise/remove neuroelectrode	Y		G2	19.1488	$792.63
61885	Insrt/redo neurostim 1 array	N		H8	275.5558	$11,406.08
61886	Implant neurostim arrays	N		H8	411.472	$17,032.06
61888	Revise/remove neuroreceiver	Y		A2	18.3275	$758.63
62194	Replace/irrigate catheter	Y		A2	7.4189	$307.09
62225	Replace/irrigate catheter	Y		A2	11.5278	$477.17
62230	Replace/revise brain shunt	Y		A2	25.7502	$1,065.88
62252	Csf shunt reprogram	N		P3	1.1676	$48.33
62263	Epidural lysis mult sessions	Y		A2	7.4189	$307.09
62264	Epidural lysis on single day	Y		A2	10.9291	$452.39
62267	Interdiscal perq aspir, dx	Y	NI	G2	4.3613	$180.53
62268	Drain spinal cord cyst	Y		A2	5.6621	$234.37

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62269	Needle biopsy, spinal cord	Y		A2	8.5923	$355.66
62270	Spinal fluid tap, diagnostic	Y		A2	3.4168	$141.43
62272	Drain cerebro spinal fluid	Y		A2	3.4168	$141.43
62273	Inject epidural patch	Y		A2	5.7017	$236.01
62280	Treat spinal cord lesion	Y		A2	7.4189	$307.09
62281	Treat spinal cord lesion	Y		A2	7.4189	$307.09
62282	Treat spinal canal lesion	Y		A2	7.4189	$307.09
62284	Injection for myelogram	N		N1		
62287	Percutaneous diskectomy	Y		A2	33.3039	$1,378.55
62290	Inject for spine disk x-ray	N		N1		
62291	Inject for spine disk x-ray	N		N1		
62292	Injection into disk lesion	Y		R2	6.9935	$289.48
62294	Injection into spinal artery	Y		A2	5.6621	$234.37
62310	Inject spine c/t	Y		A2	7.4189	$307.09
62311	Inject spine l/s (cd)	Y		A2	7.4189	$307.09
62318	Inject spine w/cath, c/t	Y		A2	7.4189	$307.09
62319	Inject spine w/cath l/s (cd)	Y		A2	7.4189	$307.09
62350	Implant spinal canal cath	Y		A2	25.7502	$1,065.88
62355	Remove spinal canal catheter	Y		A2	12.2603	$507.49
62360	Insert spine infusion device	Y		A2	25.7502	$1,065.88
62361	Implant spine infusion pump	Y		H8	264.3297	$10,941.40
62362	Implant spine infusion pump	Y		H8	264.3297	$10,941.40
62365	Remove spine infusion device	Y		A2	22.7857	$943.17
62367	Analyze spine infusion pump	N		P3	0.4182	$17.31
62368	Analyze spine infusion pump	N		P3	0.5315	$22.00
63600	Remove spinal cord lesion	Y		A2	14.2783	$591.02
63610	Stimulation of spinal cord	Y		A2	12.9471	$535.92
63615	Remove lesion of spinal cord	Y		R2	18.05	$747.14
63650	Implant neuroelectrodes	N		H8	76.8524	$3,181.15
63655	Implant neuroelectrodes	N		J8	112.57	$4,659.61
63660	Revise/remove neuroelectrode	Y		A2	13.4967	$558.67
63685	Insrt/redo spine n generator	N		H8	341.6759	$14,142.99
63688	Revise/remove neuroreceiver	Y		A2	18.3275	$758.63
63744	Revision of spinal shunt	Y		A2	26.5042	$1,097.09
63746	Removal of spinal shunt	Y		A2	12.2603	$507.49
64400	N block inj, trigeminal	Y		P3	1.3418	$55.54
64402	N block inj, facial	Y		P3	1.2635	$52.30
64405	N block inj, occipital	Y		P3	1.0717	$44.36

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64408	N block inj, vagus	Y		P3	1.3331	$55.18
64410	N block inj, phrenic	Y		A2	7.4189	$307.09
64412	N block inj, spinal accessor	Y		P3	1.9605	$81.15
64413	N block inj, cervical plexus	Y		P3	1.2548	$51.94
64415	N block inj, brachial plexus	Y		A2	3.4168	$141.43
64416	N block cont infuse, b plex	Y		G2	6.9935	$289.48
64417	N block inj, axillary	Y		A2	3.4168	$141.43
64418	N block inj, suprascapular	Y		P3	1.76	$72.85
64420	N block inj, intercost, sng	Y		A2	3.4168	$141.43
64421	N block inj, intercost, mlt	Y		A2	7.4189	$307.09
64425	N block inj, ilio-ing/hypogi	Y		P3	1.2198	$50.49
64430	N block inj, pudendal	Y		A2	5.134	$212.51
64435	N block inj, paracervical	Y		P3	1.8385	$76.10
64445	N block inj, sciatic, sng	Y		P3	1.6293	$67.44
64446	N blk inj, sciatic, cont inf	Y		G2	14.0139	$580.08
64447	N block inj fem, single	Y		R2	3.559	$147.32
64448	N block inj fem, cont inf	Y	CH	G2	3.559	$147.32
64449	N block inj, lumbar plexus	Y	CH	G2	6.9935	$289.48
64450	N block, other peripheral	Y		P3	1.0891	$45.08
64455*	N block inj, plantar digit	Y	NI	P3	0.453	$18.75
64470	Inj paravertebral c/t	Y		A2	7.4189	$307.09
64472	Inj paravertebral c/t add-on	Y		A2	5.7017	$236.01
64475	Inj paravertebral l/s	Y		A2	7.4189	$307.09
64476	Inj paravertebral l/s add-on	Y		A2	5.1349	$212.55
64479	Inj foramen epidural c/t	Y		A2	7.4189	$307.09
64480	Inj foramen epidural add-on	Y		A2	5.7017	$236.01
64483	Inj foramen epidural l/s	Y		A2	7.4189	$307.09
64484	Inj foramen epidural add-on	Y		A2	5.7017	$236.01
64505	N block, spenopalatine gangl	Y		P3	0.9934	$41.12
64508	N block, carotid sinus s/p	Y	CH	P3	2.1086	$87.28
64510	N block, stellate ganglion	Y		A2	7.4189	$307.09
64517	N block inj, hypogas plxs	Y		A2	5.134	$212.51
64520	N block, lumbar/thoracic	Y		A2	7.4189	$307.09
64530	N block inj, celiac pelus	Y		A2	7.4189	$307.09
64553	Implant neuroelectrodes	N		H8	75.5212	$3,126.05
64555	Implant neuroelectrodes	N		J8	84.8059	$3,510.37
64560	Implant neuroelectrodes	N		J8	84.8059	$3,510.37
64561	Implant neuroelectrodes	N		H8	77.6061	$3,212.35

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64565	Implant neuroelectrodes	N		J8	84.8059	$3,510.37
64573	Implant neuroelectrodes	N		H8	132.1149	$5,468.63
64575	Implant neuroelectrodes	N		H8	100.991	$4,180.32
64577	Implant neuroelectrodes	N		H8	100.991	$4,180.32
64580	Implant neuroelectrodes	N		H8	100.991	$4,180.32
64581	Implant neuroelectrodes	N		H8	103.0759	$4,266.62
64585	Revise/remove neuroelectrode	Y		A2	13.4967	$558.67
64590	Insrt/redo pn/gastr stimul	N		H8	275.5558	$11,406.08
64595	Revise/rmv pn/gastr stimul	Y		A2	18.3275	$758.63
64600	Injection treatment of nerve	Y		A2	10.9291	$452.39
64605	Injection treatment of nerve	Y		A2	10.9291	$452.39
64610	Injection treatment of nerve	Y		A2	10.9291	$452.39
64612	Destroy nerve, face muscle	Y		P3	1.5945	$66.00
64613	Destroy nerve, neck muscle	Y		P3	1.5423	$63.84
64614	Destroy nerve, extrem musc	Y		P3	1.76	$72.85
64620	Injection treatment of nerve	Y		A2	7.4189	$307.09
64622	Destr paravertebrl nerve l/s	Y		A2	10.9291	$452.39
64623	Destr paravertebral n add-on	Y		A2	7.4189	$307.09
64626	Destr paravertebrl nerve c/t	Y		A2	10.9291	$452.39
64627	Destr paravertebral n add-on	Y		A2	5.1349	$212.55
64630	Injection treatment of nerve	Y		A2	7.6419	$316.32
64632*	N block inj, common digit	Y	NI	P3	0.8277	$34.26
64640	Injection treatment of nerve	Y		P3	2.4659	$102.07
64650	Chemodenerv eccrine glands	Y		P3	0.8277	$34.26
64653	Chemodenerv eccrine glands	Y		P3	0.8975	$37.15
64680	Injection treatment of nerve	Y		A2	11.6119	$480.65
64681	Injection treatment of nerve	Y		A2	12.2603	$507.49
64702	Revise finger/toe nerve	Y		A2	12.9471	$535.92
64704	Revise hand/foot nerve	Y		A2	12.9471	$535.92
64708	Revise arm/leg nerve	Y		A2	14.2783	$591.02
64712	Revision of sciatic nerve	Y		A2	14.2783	$591.02
64713	Revision of arm nerve(s)	Y		A2	14.2783	$591.02
64714	Revise low back nerve(s)	Y		A2	14.2783	$591.02
64716	Revision of cranial nerve	Y		A2	15.032	$622.22
64718	Revise ulnar nerve at elbow	Y		A2	14.2783	$591.02
64719	Revise ulnar nerve at wrist	Y		A2	14.2783	$591.02
64721	Carpal tunnel surgery	Y		A2	14.2783	$591.02
64722	Relieve pressure on nerve(s)	Y		A2	12.9471	$535.92

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