DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, and 419

[CMS–1427–P]

RIN 0938–AM75

Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Payment Rates

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise 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 certain related provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. In addition, the proposed rule describes proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. These changes would be applicable to services furnished on or after January 1, 2005.

DATES: To be ensured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 8, 2004.

ADDRESSES: In commenting, please refer to file code CMS–1427–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically:*

You may submit electronic comments to *http://www.cms.hhs.gov/regulations/ecomments* (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word). You can assist us by referencing the ''specific identifier'' that precedes the section on which you choose to comment.

2. *By 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–1427–P, P.O. Box 8010, Baltimore, MD 21244–8018.

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

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

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–1427–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

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. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public web site. Written comments received timely will be available for public inspection as they are received, generally beginning approximately 4 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7195.

Submission of comments on paperwork requirements. For comments that relate to information collection requirements, mail a copy of comments to the following addresses:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Security and Standards Group, Office of Regulations Development and Issuances, Room C4–24–02, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: John Burke, CMS–1427–P; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503, Christopher Martin, CMS Desk Officer.

Comments submitted to OMB may also be emailed to the following address:

Christopher_Martin@omb.eop.gov, or faxed to OMB at (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Dana Burley, (410) 786–0378, Outpatient prospective payment issues and Suzanne Asplen, (410) 786–4558, Partial hospitalization and community mental health center issues.

SUPPLEMENTARY INFORMATION: *Copies:* To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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Alphabetical List of Acronyms Appearing in the Proposed Rule

ACEP American College of Emergency Physicians
AHA American Hospital Association
AHIMA American Health Information Management Association
AMA American Medical Association
APC Ambulatory payment classification
ASP Average sales price
ASC Ambulatory surgical center
AWP Average wholesale price
BBA Balanced Budget Act of 1997, Pub. L. 105–33
BIPA Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106–554
BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. 106–113
CAH Critical access hospital
CCR (Cost center specific) cost-to-charge ratio
CMHC Community mental health center
CMS Centers for Medicare & Medicaid Services (formerly known as the Health Care Financing Administration)
CORF Comprehensive Outpatient Rehabilitation Facility
CPT [Physicians'] Current Procedural Terminology, Fourth Edition, 2004, 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
DRG Diagnosis-related group
DSH Disproportionate share hospital
EACH Essential Access Community Hospital
E/M Evaluation and management
EPO Erythropoietin
ESRD End-stage renal disease
FACA Federal Advisory Committee Act, Pub. L. 92–463
FDA Food and Drug Administration
FI Fiscal intermediary
FSS Federal Supply Schedule
FY Federal fiscal year
HCPCS Healthcare Common Procedure Coding System
HCRIS Hospital Cost Report Information System
HHA Home health agency
HIPAA Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191
ICD–9–CM International Classification of Diseases, Ninth Edition, Clinical Modification
IME Indirect medical education
IPPS (Hospital) inpatient prospective payment system
IVIG Intravenous immune globulin
LTC Long-term care
MedPAC Medicare Payment Advisory Commission
MDH Medicare dependent hospital
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173
MSA Metropolitan Statistical Area
NCD National Coverage Determination
OCE Outpatient code editor
OMB Office of Management and Budget
OPD (Hospital) outpatient department
OPPS (Hospital) outpatient prospective payment system
PET Positron Emission Tomography
PHP Partial hospitalization program
PM Program memorandum
PPI Producer Price Index
PPS Prospective payment system
PPV Pneumococcal pneumonia (virus)
PRA Paperwork Reduction Act
QIO Quality Improvement Organization
RFA Regulatory Flexibility Act
RRC Rural referral center
SBA Small Business Administration
SCH Sole community hospital
SDP Single drug pricer
SI Status indicator
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248
TOPS Transitional outpatient payments
USPDI United States Pharmacopoeia Drug Information

I. Background

A. Legislative and Regulatory Authority for the 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 cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), enacted on August 5, 1997, added section 1833(t) to the Social Security Act (the Act) authorizing implementation of a PPS for hospital outpatient services. The Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), enacted on November 29, 1999, made major changes that affected the hospital outpatient PPS (OPPS). The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), enacted on December 21, 2000, made further changes in the OPPS. Section 1833(t) of the Act was also recently amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, enacted on December 8, 2003 (these amendments are discussed later under section I.E. of this proposed rule). 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 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. The OPPS includes payment for most hospital outpatient services, except those identified in section I.B. of this proposed rule and certain inpatient services covered under Medicare Part B for beneficiaries who are entitled to Part B benefits but who have exhausted them or otherwise are not entitled to them. In addition, the OPPS applies to partial hospitalization services furnished by community mental health centers (CMHCs).

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 inpatient hospital wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC 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 is more than 2 times greater than the lowest median cost for an item or service with the same APC (referred to as the ''2 times rule''). In implementing this provision, we use the median cost of the item or service assigned to an APC.

Special payments under the OPPS may be made for new technology items and services in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of medical devices for at least 2 but not more than 3 years. For new technology services that are not eligible for pass-through payments and for which we lack sufficient data to appropriately assign them to a clinical APC, we have established special APC groups based on costs, which we refer to as APC cost bands. These cost bands allow us to price these new procedures more appropriately and consistently. Like the pass-through payments, these special payments for new technology services are also temporary; that is, we retain a service within a new technology APC group until we acquire adequate data to assign it to a clinically appropriate APC.

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 excluded payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. The Secretary exercised the broad authority granted under the statute to exclude from the OPPS those services that are already 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; laboratory services paid under the clinical diagnostic laboratory fee schedule; 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 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 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. Since implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our experience with this system. For a full discussion of the changes to the OPPS, we refer readers to these **Federal Register** final rules.[1]

On November 7, 2003, we published a final rule with comment period in the **Federal Register** (68 FR 63398) that revised the OPPS to update the payment weights and conversion factor for services payable under the calendar year (CY) 2004 OPPS on the basis of claims data from April 1, 2002 through December 31, 2002. Subsequent to publishing the November 7, 2003 final rule with comment period, we published a correction of the final rule with comment period on December 31, 2003 (68 FR 75442). That document corrected technical errors in the November 7, 2003 rule and included responses to a number of public comments that were inadvertently omitted from that rule.

On January 6, 2004, we published in the **Federal Register** an interim final rule with comment period (69 FR 820) that implemented provisions of Pub. L. 108–173 that affected payments made under the OPPS, effective January 1, 2004. We will finalize this interim final rule and address public comments associated with that rule when we finalize this 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 of 1999, requires that we consult with an outside panel of experts to review the clinical integrity of the payment groups and weights under the OPPS. The Advisory Panel on APC Groups (the APC Panel), discussed under section I.D.2. of this preamble, fulfills this requirement. The Act further specifies that the Panel will act in an advisory capacity. This expert panel, which is to be composed of 15 representatives of providers subject to the OPPS (currently employed full-time, not consultants, in their respective areas of expertise), reviews and advises us about the clinical integrity of the APC groups and their weights. The APC Panel is not restricted to using our data and 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 charter establishing the Advisory Panel on APC Groups. The APC Panel is technical in nature and is governed by the provisions of the Federal Advisory Committee Act (FACA), as amended (Pub. L. 92–463). On November 1, 2002, the Secretary

[1] Interim final rule with comment period, August 3, 2000 (65 FR 47670); interim final rule with comment period, November 13, 2000 (65 FR 67798); final rule and interim final rule with comment period, November 2, 2001 (66 FR 55850 and 55857); final rule, November 30, 2001 (66 FR 59856); final rule, December 31, 2001 (66 FR 67494); final rule, March 1, 2002 (67 FR 9556); final rule, November 1, 2002 (67 FR 66718); interim final rule with comment period, November 7, 2003 (68 FR 63398); and interim final rule with comment period, January 6, 2004 (69 FR 820).

renewed the charter. The renewed charter indicates 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, and is chaired by a Federal official.

Originally, in establishing the APC Panel, we solicited members in a notice published in the **Federal Register** on December 5, 2000 (65 FR 75943). We received applications from more than 115 individuals nominating either colleagues or themselves. After carefully reviewing the applications, we chose 15 highly qualified individuals to serve on the APC Panel. Because of the loss of four APC Panel members due to the expiration of terms of office on March 31, 2004, we published a **Federal Register** notice on January 23, 2004 (69 FR 3370) that solicited nominations for APC Panel membership. From the 24 nominations that we received, we chose four new members. The entire APC Panel membership is identified on the CMS website at *www.cms.hhs.gov/faca/apc/apcmem.asp*.

3. APC Panel Meetings and Organizational Structure

The APC Panel first met on February 27, February 28, and March 1, 2001. Since that initial meeting, the APC Panel has held four subsequent meetings, with the last meeting taking place on February 18, 19, and 20, 2004. Prior to each of these biennial meetings, we published a notice in the **Federal Register** to announce each meeting and, when necessary, to solicit nominations for APC Panel membership. For a more detailed discussion about these announcements, refer to the following **Federal Register** notices: December 5, 2000 (65 FR 75943), December 14, 2001 (66 FR 64838), December 27, 2002 (67 FR 79107), July 25, 2003 (68 FR 44089), and December 24, 2003 (68 FR 74621).

During these meetings, the APC Panel established its operational structure which, in part, includes the use of three subcommittees to facilitate its required APC review process. Currently, the three subcommittees are the Data Subcommittee, the Observation Subcommittee, and the Packaging Subcommittee. The Data Subcommittee is responsible for studying the data issues confronting the APC Panel and for recommending viable options for resolving them. This subcommittee was initially established on April 23, 2001, as the Research Subcommittee and reestablished as the Data Subcommittee on April 13, 2004. The Observation Subcommittee (established on June 24, 2003, and reestablished with new members on March 8, 2004) reviews and makes recommendations to the APC Panel on all issues pertaining to observation services paid under the OPPS, such as coding and operational issues. The Packaging Subcommittee, which was established on March 8, 2004, studies and makes recommendations on issues pertaining to services that are not separately payable under the OPPS but are bundled or packaged into the APC payment. Each of these subcommittees was established by a majority vote of the APC Panel during a scheduled annual or biennial APC Panel meeting. All subcommittee recommendations are discussed and voted upon by the full APC Panel.

For a detailed discussion of the APC Panel meetings, refer to the hospital OPPS final rules cited in section I.C. of this preamble. A full discussion of the APC Panel's February 2004 meeting and the resulting recommendations is included in sections II., III., IV., V., and VI. of this preamble.

E. Provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108–173, was enacted. Pub. L. 108–173 made changes to the Act relating to the Medicare OPPS. In a January 6, 2004 interim final rule with comment period, we implemented provisions of Pub. L. 108–173 relating to the OPPS that were effective for CY 2004. In this proposed rule, we are proposing to implement the following sections of Pub. L. 108–173 that are effective for CY 2005:

- Section 611, which provides for Medicare coverage of an initial preventive physical examination under Part B, subject to the applicable deductible and coinsurance, as an outpatient department (OPD) service payable under the OPPS. The provisions of section 611 apply to services furnished on or after January 1, 2005, but only for individuals whose coverage period under Medicare Part B begins on or after that date.
- Section 614, which provides that screening mammography and diagnostic mammography services are excluded from payment under the OPPS. This amendment applies to screening mammography services furnished on or after the date of enactment of Pub. L. 108–173 (that is, December 8, 2003), and in the case of diagnostic mammography, to services furnished on or after January 1, 2005.
- Section 621(a)(1), which requires special classification of certain separately paid radiopharmaceutical agents and drugs or biologicals, and specifies the pass-through payment percentages, effective for services furnished on or after January 1, 2005, for the three categories of "specified covered OPD drugs'' defined in the statute: sole source drug; innovator multiple source drug; and noninnovator multiple source drug. In addition, payment for these drugs for CYs 2004 and 2005 does not have to be made in a budget neutral manner.
- Section 621(a)(2), which specifies the reduced threshold for the establishment of separate APCs with respect to drugs or biologicals from $150 to $50 per administration for drugs and biologicals furnished in CYs 2005 and 2006.
- Section 621(a)(3), which excludes separate drug APCs from outlier payments. Specifically, no additional payment will be made in the case of APC groups established separately for drugs and biologicals.
- Section 621(b), which requires that all devices of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2007, be paid based on the hospital's charges for each device, adjusted to cost. This provision also requires that these brachytherapy services be excluded from outlier payments.

F. Summary of Major Content of This Proposed Rule

In this proposed rule, we are setting forth proposed changes to the Medicare hospital OPPS. These changes would be effective for services furnished on or after January 1, 2005. The following is a summary of the major changes that we are proposing to make:

1. Proposed Changes to the APCs Groups

As required by section 1833(t)(9)(A) of the Act, we are proposing the annual update of the APC groups and the relative payment weights. This section also requires that we consult with an outside panel of experts, the Advisory Panel on APC Groups, to review the clinical integrity of the groups and weights under the OPPS. Based on analyses of Medicare claims data and recommendations of the APC Panel, we are proposing to establish a number of new APCs and to make changes to the assignment of HCPCS codes under a number of existing APCs. Our proposed APC changes for CY 2005 are set forth in section II. of this preamble.

We also discuss the application of the 2 times rule and proposed exceptions to it; coding for stereotactic radiosurgery services; the proposed movement of

procedures from the new technology APCs; the proposed changes to the list of procedures that will be paid as inpatient services; and the proposed additions of new procedure codes to the APCs.

2. Recalibrations of APC Relative Payment Weights

In section III. of this preamble, we discuss the methodology used to recalibrate the proposed APC relative payment weights and set forth the proposed recalibration of the relative weights for CY 2005.

3. Proposed Payment Changes for Devices

In section IV. of this preamble, we discuss proposed changes to the pass-through payment for devices and the methodology used to reduce transitional pass-through payments to offset costs packaged into APC groups.

4. Proposed Payment Changes for Drugs, Biologicals, Radiopharmaceutical Agents, and Blood and Blood Products

In section V. of this preamble, we discuss our proposed payment changes for drugs, biologicals, radiopharmaceutical agents, and blood and blood products.

5. Pro Rata Reduction for Transitional Pass-Through Drugs, Biologicals, and Devices

In section VI. of this preamble, we discuss the proposed methodology for measuring whether there should be an estimated pro rata reduction for transitional pass-through drugs, biologicals, and devices for CY 2005.

6. Other Policy Decisions and Proposed Policy Changes

In section VII. of this preamble, we present our proposals for CY 2005 regarding the following:

- Update of statewide default cost-to-charge ratios.
- A conforming change to the regulation relating to the use of the first available cost reporting period ending after 1996 and before 2001 for determining a provider's payment-to-cost ratio to calculate transitional corridor payments for hospitals paid under the OPPS that did not have a 1996 cost report.
- Proposed changes in the status indicators and comment indicators assigned to APCs for CY 2005.
- Proposed elimination of the diagnostic tests criteria as a requirement for hospitals to qualify for separate payment of observation services under APC 0339 (Observation) and changes to the guidelines to hospitals for counting patients time spent in observation care.
- Proposed payment under the OPPS for certain procedures currently assigned to the inpatient list.
- Proposed strategy for giving the public notice of new implementation guidelines for new evaluation and management codes.
- Proposed addition of three new HCPCS codes and descriptors for brachytherapy sources that would be paid separately, pursuant to Pub. L. 108–173.
- Proposed modification of the HCPCS code descriptors for brachytherapy source descriptors for which units of payment are not already delineated.
- Proposed payment for services furnished emergently to an outpatient who dies before admission to a hospital as an inpatient.

7. Proposed Conversion Factor Update for CY 2005

As required by section 1833(5)(3)(C)(ii) of the Act, under section VIII. of this preamble, we are proposing to update the conversion factor used to determine payment rates under the OPPS for CY 2005.

8. Proposed Wage Index Changes for CY 2005

In section IX. of this preamble, we discuss the proposed retention of our current policy to apply the IPPS wage indices to wage adjust the APC median costs in determining the OPPS payment rate and the copayment standardized amount. These indices reflect proposed major changes for CY 2005 relating to hospital labor market areas as a result of OMB revised definitions of geographical statistical areas; hospital reclassifications and redesignations, including the one-time reclassifications under section 508 of Pub. L. 108–173; and the wage index adjustment based on commuting patterns of hospital employees under section 505 of Pub. L. 108–173.

9. Determination of Payment Rates and Outlier Payments for CY 2005

In section X. of this preamble, we discuss how APC payment rates are calculated and how the payment rates are adjusted to reflect geographic differences in labor-related costs. This section also discusses proposed changes in the way we calculate outlier payments for CY 2005.

10. MedPAC Recommendations

Under section 1805(b) of the Act, the Medicare Payment Advisory Committee (MedPAC) is required to submit a report to Congress, no later than March 1 of each year, that reviews and makes recommendations on Medicare payment policies. This annual report makes recommendations concerning the hospital outpatient prospective payment system. In section XII. of this preamble, we discuss the MedPAC recommendations. For further information relating specifically to the MedPAC March 1, 2004 report or to obtain a copy of the report, visit MedPAC's Web site at: *http://www.medpac.gov*.

11. Regulatory Impact Analysis

In section XV. of this preamble, we set forth our analysis of the impact that the proposed changes contained in this proposed rule would have on affected hospitals and CMHCs.

II. Proposed Changes Related to Ambulatory Payment Classifications (APCs)

[If you choose to comment on issues in this section, please indicate the caption "APC Groups'' at the beginning of your comment.]

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) 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 the Ambulatory Payment Classifications Groups or APCs, as set forth in § 419.31 of the regulations. We use Healthcare Common Procedure Coding System (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. (However, new technology APCs that are temporary groups for certain approved services are structured based on cost rather clinically homogeneity.) Using this classification system, we have established distinct groups of surgical, diagnostic, and partial hospitalization services, and medical visits. Because of the transitional pass-through provisions, we also have developed separate APC groups for certain medical devices, drugs, biologicals, radiopharmaceuticals, and devices of brachytherapy.

We have packaged into each procedure or service within an APC the cost associated with those items or services that are directly related and integral to performing a procedure or furnishing a service. Therefore, we would not make separate payment for

packaged items or services. For example, packaged items and services include: use of an operating, treatment, or procedure room; use of a recovery room; use of an observation bed; anesthesia; medical/surgical supplies; pharmaceuticals (other than those for which additional payment may be allowed under the transitional pass-through provisions discussed in section V. of this preamble); and incidental services such as venipuncture. Our packaging methodology is discussed in section IV.B.3. of this proposed rule.

A. Proposed APC Changes: General

Under the OPPS, we pay for hospital outpatient services on a rate-per-service basis that varies according to the APC group to which the service is assigned. Each APC weight represents the median hospital cost of the services included in that APC relative to the median hospital cost of the services included in APC 601, Mid-Level Clinic visits. The APC weights are scaled to APC 601 because a mid-level clinic visit is one of the most frequently performed services in the 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 of 1999, 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.

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 (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 (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.

Section 419.31 of the regulations sets forth the requirements for the APC system and determination of the payment weights. In this section, we discuss the changes that we are proposing to the APC groups; the APC Panel's review and recommendations and our proposals in response to those recommendations; the application of the 2 times rule and proposed exceptions to it; coding for stereotactic radiosurgery services; the proposed movement of procedures from the new technology APCs; the proposed changes to the inpatient list; and the proposed additions of new procedures codes to the APCs.

B. APC Panel Review and Recommendations

As stated above, the APC Panel met on February 18, 19, and 20, 2004, to discuss the revised APCs for the CY 2005 OPPS. In preparation for that meeting, we published a notice in the **Federal Register** on December 24, 2004 (68 FR 74621), to announce the location, date, and time of the meeting; the agenda items; and the fact that the meeting was open to the public. In that notice, we solicited public comment specifically on the items included on the agenda for that meeting. We also provided information about the APC Panel meeting on the CMS website: *www.cms.hhs.gov/faca/apc/panel.*

Oral presentations and written comments submitted for the February 2004 APC Panel meeting met, at a minimum, the adopted guidelines for presentations set forth in the **Federal Register** document (68 FR 74621). Below is a summary of the APC issues discussed by the APC Panel, its recommendations, and our proposals with respect to those recommendations. The discussion in this section is limited to proposed APC changes regarding APCs other than those that violate the 2 times rule and those that represent drugs, biologicals, and transitional pass-through devices, or those that are new technology APCs. The specific APC Panel review and recommendations applicable to those APCs are discussed in sections II.C., IV., III., and II.F., respectively, of the preamble to this proposed rule. In conducting its APC review, the APC Panel heard testimony and received evidence in support of the testimonies from a number of interested parties. The APC Panel also used hospital outpatient claims data for the period January 1, 2003, through September 30, 2003, that provided, at a minimum, median costs for the APC structure in place in CY 2004 and that was based on cost-to-charge ratios used for setting the CY 2004 payment rates. The data set presented to the APC Panel represented 9 months of the CY 2003 data that we are proposing to use to recalibrate the APC relative weights and to calculate the proposed APC payment rates for CY 2005. For this discussion, we are using the APC titles as published in our November 7, 2003 final rule with comment period, which were the APC titles that existed when the APC Panel met in February 2004. Because we are proposing to retitle some of the APCs, the titles used in this discussion may not be the same as those listed in Addendum A to this proposed rule.

1. APC 0018: Biopsy of Skin/Puncture of Lesion

One presenter requested that the APC Panel recommend moving CPT tracking codes 0046T (Catheter lavage, mammary duct(s)) and 0047T (Each additional duct) from APC 0018 and placing them in an APC that more accurately reflects each of the procedures. The APC Panel recommended that we reassign CPT codes 0046T and 0047T to APC 0021, Level III Excision/Biopsy.

We are proposing to accept the APC Panel's recommendation.

2. Level I and II Arthroscopy

APC 0041: Level I Arthroscopy
APC 0042: Level II Arthroscopy

We testified before the APC Panel regarding a comment that we received in 2003 requesting that we reassign CPT code 29827 (Arthroscopy, shoulder with rotator cuff repair) from APC 0041 to APC 0042, based on its similarity to CPT 29826 (Arthroscopy, shoulder decompression of subacromial space with partial acromioplasty without coracoacromial release). Our clinical staff considered the request and determined that APCs 0041 and 0042 should be reconfigured to improve clinical homogeneity. An APC Panel presenter provided evidence to support moving CPT code 29827 to an APC that would more accurately recognize the complexity of that procedure. We requested the APC Panel's recommendation regarding a total revision of these two APCs.

The APC Panel recommended that we reevaluate the codes in APCs 0041 and 0042 and propose restructuring that would improve the clinical homogeneity in the two APCs.

We are proposing to accept the APC Panel's recommendation and to revise APCs 0041 and 0042 as shown in Tables 1 and 2 below.

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Table 1.--Proposed Reconstructed APC 0041: Level I Arthroscopy

CPT/HCPCS Code	Description
29850	Knee arthroscopy/surgery
29870	Knee arthroscopy/diagnostic
29871	Knee arthroscopy/drainage
29873	Knee arthroscopy/surgery
29874	Knee arthroscopy/surgery
29875	Knee arthroscopy/surgery
29876	Knee arthroscopy/surgery
29877	Knee arthroscopy/surgery
29879	Knee arthroscopy/surgery
29880	Knee arthroscopy/surgery
29881	Knee arthroscopy/surgery
29882	Knee arthroscopy/surgery
29883	Knee arthroscopy/surgery
29884	Knee arthroscopy/surgery
29886	Knee arthroscopy/surgery
29805	Shoulder arthroscopy/diagnostic
29819	Shoulder arthroscopy/surgery
29820	Shoulder arthroscopy/surgery
29821	Shoulder arthroscopy/surgery
29822	Shoulder arthroscopy/surgery
29823	Shoulder arthroscopy/surgery
29825	Shoulder arthroscopy/surgery
29834	Elbow arthroscopy/surgery
29835	Elbow arthroscopy/surgery
29836	Elbow arthroscopy/surgery
29837	Elbow arthroscopy/surgery
29838	Elbow arthroscopy/surgery
29840	Wrist arthroscopy
29843	Wrist arthroscopy/surgery
29844	Wrist arthroscopy/surgery
29845	Wrist arthroscopy/surgery
29846	Wrist arthroscopy/surgery
29848	Wrist arthroscopy/surgery
29891	Wrist endoscopy/surgery
29892	Ankle arthroscopy/surgery
29894	Ankle arthroscopy/surgery
29895	Ankle arthroscopy/surgery
29897	Ankle arthroscopy/surgery
29898	Ankle arthroscopy/surgery
29804	Jaw arthroscopy/surgery
29999	Arthroscopy of joint
0012T	Osteochondral knee autograft
0014T	Meniscal transplant, knee
29830	Elbow arthroscopy
29860	Hip arthroscopy, dx
29887	Knee Arthroscopy/surgery

Table 2.--Proposed Reconstructed APC 0042: Level II Arthroscopy

CPT/HCPCS Code	Description
29851	Knee arthroscopy/surgery
29885	Knee arthroscopy/surgery
29888	Knee arthroscopy/surgery
29889	Knee arthroscopy/surgery
29806	Shoulder arthroscopy/surgery
29807	Shoulder arthroscopy/surgery
29824	Shoulder arthroscopy/surgery
29826	Shoulder arthroscopy/surgery
29827	Arthroscopic rotator cuff repair
29847	Wrist arthroscopy/surgery
29855	Tibial arthroscopy/surgery
29856	Tibial arthroscopy/surgery
29899	Ankle arthroscopy/surgery
29800	Jaw arthroscopy/surgery
0013T	Osteochondral knee allograft
29861	Hip arthroscopy/surgery
29862	Hip arthroscopy/surgery
29863	Hip arthroscopy/surgery

3. Angiography and Venography Except Extremity

APC 0279: Level II Angiography and Venography Except Extremity
APC 0280: Level III Angiography and Venography Except Extremity
APC 0668: Level I Angiography and Venography Except Extremity

As requested by the APC Panel, we presented our proposal for reconfiguring APCs 0279, 0280, and 0668 that reflected changes based on prior input with outside clinical experts. The APC Panel had previously reviewed these APCs during its January 2003 meeting and had recommended that we not restructure these three APCs until we received input from clinical experts in the field. When we updated the APC groups in CY 2003, we accepted the APC Panel's recommendation and made no changes to APCs 0279, 0280, and 0668.

A review of these APCs was prompted by a commenter who requested that we move CPT code 75978 (Repair venous blockage) from APC 0668 to APC 0280 and that we move CPT code 75774 (Artery x-ray, each vessel) from APC 0668 to APC 0279. The commenter submitted evidence in support of these requests and testified before the APC Panel regarding the common use of CPT code 75978 for treating dialysis patients and the often required multiple intraoperative attempts to succeed with this procedure for such patients.

After receiving input from the clinical experts, we determined that these three APCs should be revised to improve their clinical homogeneity. We presented our proposed restructuring of APCs 0279, 0280, and 0668 to the APC Panel. The APC Panel concurred with our proposal.

In addition, subsequent to the APC Panel meeting, we discovered several procedures in these APCs that were more appropriately placed in another APC in order to remedy any 2 times rule violations. Tables 3, 4, and 5 reflect those additional APC reassignments as well as those we presented to the APC Panel in February 2004.

Table 3.—Proposed Restructured APC 0668: Level I Angiography and Venography Except Extremity

CPT/HCPCS Code	Description	CY 2004 APC
75660	Artery x-rays, head and neck	0279
75705	Artery x-rays, spine	0279
75733	Artery x-rays, adrenals	0280
75960	Transcatheter introduction, stent	0280
75961	Retrieval, broken catheter	0280
75962	Repair arterial blockage, peripheral artery	0280
75964	Repair artery blockage, each	0280
75966	Repair arterial blockage, renal or other visceral	0280
75968	Repair arterial blockage, each additional visceral	0280
75970	Vascular biopsy	0280
75978	Repair venous blockage	0668

Table 4.—Proposed Restructured APC 0279: Level II Angiography and Venography Except Extremity

CPT/HCPCS Code	Description	CY 2004 APC
75658	Artery x-rays, arm	0280
75741	Artery x-rays, lung	0279
75746	Artery x-rays, lung	0279
75756	Artery x-rays, chest	0279
75774	Artery x-rays, each vessel	0668
75810	Vein x-ray, spleen/liver	0279
75825	Vein x-ray, trunk	0279
75827	Vein x-ray, chest	0279
75833	Vein x-rays, kidneys	0279
75887	Vein x-ray, liver	0280
75891	Vein x-ray, liver	0279
75992	Atherectomy, x-ray exam	0280
75993	Atherectomy, x-ray exam	0280
75994	Atherectomy, x-ray exam	0280
75995	Atherectomy, x-ray exam	0280
75996	Atherectomy, x-ray exam	0280

Table 5. –Proposed Restructured APC 280: Level III Angiography and Venography Except Extremity

CPT/HCPCS Code	Description	CY 2004 APC
75600	Contrast x-ray exam of aorta	0280
75605	Contrast x-ray exam of aorta	0280
75625	Contrast x-ray exam of aorta	0280
75630	X-ray aorta, leg arteries	0280
75650	Artery x-rays, head and neck	0280
75662	Artery x-rays, head and neck	0279
75665	Artery x-rays, head and neck	0280
75671	Artery x-rays, head and neck	0280
75676	Artery x-rays, neck	0280
75680	Artery x-rays, neck	0280
75685	Artery x-rays, spine	0279
75710	Artery x-rays, arm/leg	0280
75716	Artery x-rays, arms/legs	0280
75722	Artery x-rays, kidney	0280
75724	Artery x-rays, kidneys	0280
75726	Artery x-rays, abdomen	0280
75731	Artery x-rays, adrenal gland	0280
75736	Artery x-rays, pelvis	0280
75743	Artery x-rays, lungs	0280
75885	Vein x-ray, liver	0279
75889	Vein x-ray, liver	0279

C. Limits on Variations Within APCs: Proposed Application of the 2 Times Rule

Section 1833(t)(2) of the Act provides that the items and services within an APC group cannot be considered comparable with respect to the use of resources if the median 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. However, the statute authorizes the Secretary 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. No exception may be made in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act. We implemented this statutory provision in § 419.31 of the regulations. Under this regulation, we elected to use the highest median cost and lowest median cost to determine comparability.

During the APC Panel's February 2004 meeting, we presented data and information concerning a number of APCs that violate the 2 times rule and asked the APC Panel for its recommendation. We discuss below the APC Panel's recommendations specific to each of these APCs and our proposals in response to the APC Panel's recommendations.

1. Cardiac and Ambulatory Blood Pressure Monitoring

APC 0097: Cardiac and Ambulatory Blood Pressure Monitoring

We expressed concern to the APC Panel that APC 0097 appears to violate the 2 times rule. We sought the APC Panel's recommendation on revising the APC to address the violation. Based on clinical homogeneity considerations, the APC Panel recommended that we not restructure APC 0097 for CY 2005.

We are proposing to accept the APC Panel's recommendation that we make no changes to APC 0097 for CY 2005.

2. Electrocardiograms

APC 0099: Electrocardiograms

We expressed concern to the APC Panel that APC 0099 appears to violate the 2 times rule. We asked the APC Panel to recommend options for resolving this violation. Based on clinical homogeneity considerations, the APC Panel recommended that we not alter the structure of APC 0099 for CY 2005.

We are proposing to accept the APC Panel's recommendation that we make no changes to APC 0099 for CY 2005.

3. Excision/Biopsy

APC 0019: Level I Excision/Biopsy
APC 0020: Level II Excision/Biopsy
APC 0021: Level III Excision/Biopsy

We expressed concern to the APC Panel that APC 0019 appears to violate the 2 times rule. We advised the APC Panel that this violation was not evident in CY 2004 because the CY 2002 median cost data used in calculating the CY 2004 APC updates supported moving CPT codes 11404 (Removal of skin lesion) and 11623 (Removal of skin lesion) from APC 0020 and APC 0021. However, based on the CY 2003 data reviewed by the APC Panel, APC 0019 would violate the 2 times rule. Therefore, we asked the APC Panel to recommend an approach to resolve the violation. We asked the APC Panel if we should leave this APC as is; divide APC 0019 into two separate APCs; or move some codes in APC 0019 to higher level

excision/biopsy APCs. In making its recommendation, the APC Panel noted that the 2 times violation in APC 0019 was minor, and recommended that we not modify APC 0019.

We are proposing to accept the APC Panel's recommendation to not make any modifications to APC 0019 for CY 2005.

4. Posterior Segment Eye Procedures

APC 0235: Level I Posterior Segment Eye Procedures

We expressed concern to the APC Panel that APC 0235 appears to violate the 2 times rule. At the August 2003 APC Panel meeting, the APC Panel recommended that we monitor the data for APC 0235 for review at its February 2004 meeting. In order to address the apparent violation, we asked the APC Panel to consider moving a few CPT codes from APC 0235 into a higher level posterior segment eye procedure APC. The APC Panel noted that the 2 times violation in APC 0235 was minor, and recommended that we not change APC 0235.

We are proposing to accept the APC Panel's recommendation that we make no changes to the structure of APC 0235 for CY 2005.

5. Laparoscopy

APC 0130: Level I Laparoscopy

APC 0131: Level II Laparoscopy

We expressed concern to the APC Panel that APC 0130 appears to violate the 2 times rule. We suggested moving CPT code 44970 (Laparoscopy, appendectomy) from APC 0130 to APC 0131. The APC Panel recommended that we make this change.

We are proposing to accept the APC Panel's recommendation to move CPT code 44970 from APC 0130 to APC 0131.

6. Anal/Rectal Procedures

APC 0148: Level I Anal/Rectal Procedure

APC 0155: Level II Anal/Rectal Procedure

APC 0149: Level III Anal/Rectal Procedure

APC 0150: Level IV Anal/Rectal Procedure

We expressed concern to the APC Panel that APC 0148 appears to violate the 2 times rule. We suggested moving CPT code 46020 (Placement of seton) from APC 0148 to a higher level anal/rectal procedure APC. The APC Panel reviewed the four anal/rectal APCs (APC 0148, 0149, 0150, and 0155) and recommended moving CPT codes 46020 and 46706 (Repair of anal fistula with glue) from APC 0148 to APC 0150. The APC Panel also recommended moving CPT codes 45005 (Drainage of rectal abscess) and 45020 (Drainage of rectal abscess) from APC 0148 to APC 0155.

We are proposing to accept the APC Panel's recommendations specific to APC 0148. Our proposed movement of CPT codes from APC 0148 to APCs 0150 and 0155 is shown in the Table 6 below.

Table 6.—Proposed Movement of Anal/Rectal Procedures from APC 0148 to APC 0150 and APC 0155

CPT/HCPCS	Description	CY 2004 APC	Proposed CY 2005 APC
46020	Placement of seton	0148	0150
46706	Repair anal fistula with glue	0148	0150
45005	Drainage of rectal abscess	0148	0155
45020	Drainage of rectal abscess	0148	0155

7. Nerve Injections

APC 0204: Level I Nerve Injections
APC 0206: Level II Nerve Injections
APC 0207: Level III Nerve Injections
APC 0203: Level IV Nerve Injections

We again expressed concern to the APC Panel that APC 0203 and APC 0207 appear to violate the 2 times rule. We previously discussed this issue at the APC Panel's CY 2003 meeting. During the CY 2003 meeting, the APC Panel recommended that we gather additional data on procedures assigned to APC 0203 and APC 0207 before proposing to reconfigure them to attempt to eliminate the 2 times rule violation. The APC Panel believed then that the structure of these two APCs as proposed in the August 2003 OPPS proposed rule were more clinically cohesive than those set forth in the November 2002 OPPS final rule. During the February 2004 meeting, we presented other information for the APC Panel to review in making its recommendation.

After careful consideration of the new data, the APC Panel recommended moving CPTs 64420 (Nerve block injection, intercostal nerve), 64630 (Injection treatment of nerve), 64640 (Injection treatment of nerve), and 62280 (Treatment of a spinal cord lesion) from APC 0207 to APC 0206. The APC Panel also recommended moving CPT code 62282 (Treatment of a spinal canal lesion) from APC 0207 to APC 0203.

After reviewing more recent, complete calendar year data, we are proposing to accept some of the APC Panel's recommendation (specifically, move CPTs 64630 and 64640 from APC 0207 to APC 0206), and to make some other changes that we believe are appropriate to improve the nerve injection APC's clinical and resource homogeneity. Our proposed nerve injection APC assignments are shown in Tables 7, 8, and 9 below.

Table 7.—Proposed Movement of Level III: Nerve Injections CPT Codes from APC 0207 to APC 0204 and APC 0206

CPT/HCPCS	Description	CY 2004 APC	Proposed CY 2005 APC
64420	Nerve block injection, intercostal nerve	0207	0204
64630	Injection treatment of nerve	0207	0206
64640	Injection treatment of nerve	0207	0206
64421	Nerve block injection, intercostals, multiple	0207	0206
64472	Injection paravertebral cervical/thoracic, add-on	0207	0206
64476	Injection paravertebral lumbosacral, add-on	0207	0206
64630	Injection treatment of nerve	0207	0206
64640	Injection treatment of nerve	0207	0206

Table 8.—Proposed Movement of Level I: Nerve Injections CPT Codes from APC 0204 to APC 0206

CPT/HCPCS	Description	CY 2004 APC	Proposed CY 2005 APC
G0260	Injection for sacroiliac joint anesthesia	0204	0206
64410	Nerve block injection, phrenic	0204	0206
64412	Nerve block injection, spinal accessory	0204	0206
64446	Nerve block injection, sciatic, continuous infusion	0204	0206
61791	Treatment of a trigeminal tract	0204	0206

Table 9.—Proposed Movement of Level II: Nerve Injections CPT Codes from APC 0206 to APC 0204 and APC 0207

CPT/HCPCS	Description	CY 2004 APC	Proposed CY 2005 APC
62270	Spinal fluid tap, diagnostic	0206	0204
62272	Drainage of cerebrospinal fluid	0206	0204
62310	Injection of spine cervical/thoracic	0206	0207
62311	Injection of spine lumbar/sacral (cd)	0206	0207
62318	Injection of spine with catheter, cervical/thoracic	0206	0207
62319	Injection of spine with catheter Lumbar/sacral (cd)	0206	0207

8. Anterior Segment Eye Procedures

APC 0232: Level I Anterior Segment Eye Procedures

APC 0233: Level II Anterior Segment Eye Procedures

We expressed concern to the APC Panel that APC 0233 appears to violate the 2 times rule. We suggested moving CPT codes 65286 (Repair of eye wound), 66030 (Injection treatment of eye), and 66625 (Removal of iris) from APC 0233 to APC 0232. The APC Panel agreed and recommended that we move CPT codes 65286, 66030, and 66625 from APC 0233 to APC 0232.

We are proposing to accept the APC Panel's recommendation and to reassign these three codes as shown in Table 10.

Table 10.—Proposed Reassignment of Anterior Segment Eye Procedures Codes From APC 0233 to APC 0232

CPT/HCPCS	Description	CY 2004 APC	Proposed CY 2005 APC
65286	Repair of eye wound	0233	0232
66030	Injection treatment of eye	0233	0232
66625	Removal of iris	0233	0232

9. Pathology

APC 0343: Level II Pathology

APC 0344: Level III Pathology

We expressed concern to the APC Panel that APC 0343 appears to violate the 2 times rule. We suggested moving CPT code 88346 (Immunoflourescent study) from APC 0343 to APC 0344. The APC Panel concurred with our proposal.

We are proposing to accept the APC Panel's recommendation and to move CPT code 88346 from APC 0343 to APC 0344.

10. Immunizations

APC 0355: Level III Immunizations (proposed for CY 2005: Level I Immunizations)

APC 0356: Level IV Immunizations (proposed for CY 2005: Level II Immunizations)

We expressed concern to the APC Panel that APCs 0355 and 0356 appear to violate the 2 times rule. In order to eliminate this violation, we suggested moving CPT 90636 (Hepatitis A/Hepatitis B vaccine, adult dose, intramuscular use) from APC 0355 to APC 0356. We also suggested moving CPT codes 90375 (Rabies immune globulin, intramuscular or subcutaneous), 90740 (Hepatitis B vaccine, dialysis or immunosuppressed patient, intramuscular), 90723 (Diphtheria-pertussis-tetanus, Hepatitis B, Polio vaccine, intramuscular), and 90693 (Typhoid vaccine, AKD, subcutaneous) from APC 0356 to APC 0355.

The APC Panel recommended moving CPT 90636 from APC 0355 to APC 0356 and CPT codes 90740, 90723, and 90693 from APC 0356 to APC 0355. The APC Panel delayed making a recommendation on CPT 90375 and requested that we collect additional cost data on this procedure for discussion at the next scheduled APC Panel meeting.

We are proposing to accept the APC Panel's recommended changes to move CPT code 90740 from APC 0356 to 0355, and to move CPT code 90636 from 0355 to 0356. However, based on our review of more recent claims data than were available to the APC Panel, we determined that the medians for CPT

codes 90693 and 90375 are below the $50 drug packaging threshold. Therefore, we are also proposing to package both CPT codes 90693 and 90375. We are proposing to change CPT code 90723 to status indicator "e'' because it is not payable by Medicare.

Table 11.—Proposed Movement of Immunization CPT Codes Between APC 0355 and APC 0356

CPT/HCPCS	Description	CY 2004 APC	Proposed CY 2005 APC
90636	Hepatitis A/Hepatitis B vaccine, adult dose, intramuscular use	0355	0356
90740	Hepatitis B vaccine, dialysis or immunosuppressed patient	0356	0355

11. Pulmonary Tests

APC 0367: Level I Pulmonary Tests
APC 0368: Level II Pulmonary Tests
APC 0369: Level III Pulmonary Tests

We expressed concern to the APC Panel that APC 0369 appears to violate the 2 times rule. We suggested moving CPT code 94015 (Patient recorded spirometry) from APC 0369 to APC 0367. The APC Panel concurred with our proposal.

We are proposing to accept the APC Panel's recommendation and to move CPT code 94015 from APC 0369 to APC 0367.

In addition, during our analysis of more recent claims data following the APC Panel meeting, we noted that APC 0367 violated the 2 times rules. Therefore, we are proposing to reassign CPT codes 94375, 94750, 94450, 94014, 94690, and 93740 to APC 0368.

Table 12.—Proposed Reassignment of Certain CPT Codes Among APCs 0367, 0368 and 0369

HCPCS	Description	CY 2004 APC	Proposed CY 2005 APC
94015	Patient recorded spirometry	0369	0367
94375	Respiratory flow volume loop	0367	0368
94750	Pulmonary compliance study	0367	0368
94450	Hypoxia response curve	0367	0368
94014	Patient recorded spirometry	0367	0368
94690	Exhaled air analysis	0367	0368
93740	Temperature gradient studies	0367	0368

12. Clinic Visits

APC 0600: Low Level Clinic Visits

We expressed concern to the APC Panel that APC 0600 appears to violate the 2 times rule. We suggested moving HCPS code G0264 (Assessment other than CHF, chest pain, asthma) to a higher level clinic visit. The APC Panel recommended that we not make any changes to APC 0600.

We are proposing to accept this recommendation and not make any changes to APC 0600 for CY 2005.

D. Proposed Exceptions to the 2 Times Rule

[If you choose to comment on issues in this section please indicate the caption "2 Times Rule'' at the beginning of your comment.]

As discussed earlier, the Secretary is authorized to make exceptions to the 2 times limit on the variation of costs within each APC group in unusual cases such as low volume items and services.

Taking into account the APC changes that we are proposing for CY 2005 based on the APC Panel recommendations discussed in section II.C. of this preamble and the use of CY 2003 claims data to calculate the median cost of procedures classified in the APCs, we reviewed all the APCs to determine which of them would not meet the 2

times limit. We used the following criteria when deciding whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity
- Clinical homogeneity
- Hospital concentration
- Frequency of service (volume)
- Opportunity for upcoding and code fragments.

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

Table 13 contains the APCs that we are proposing to exempt from the 2 times rule based on the criteria cited above. In cases in which a recommendation of 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 these recommendations were based on explicit consideration of resource use, clinical homogeneity, hospital specialization, and the quality of the data used to determine the APC payment rates that we are proposing for CY 2005. The median cost for hospital outpatient services for these and all other APCs can be found at web site: *http//www.cms.hhs.gov.*

Table 13.-- Proposed APCs Exceptions to the 2 Times Rule

Proposed Rule APC	Description
0019	Level I Excision/Biopsy
0024	Level I Skin Repair
0032	Insertion of Central Venous/Arterial Catheter
0043	Closed Treatment Fracture Finger/Toe/Trunk
0046	Open/Percutaneous Treatment Fracture or Dislocation
0060	Manipulation Therapy
0080	Diagnostic Cardiac Catheterization
0087	Cardiac Electrophysiologic Recording/Mapping
0093	Vascular Reconstruction/Fistula Repair without Device
0099	Electrocardiograms
0105	Revision/Removal of Pacemakers, AICD, or Vascular
0121	Level I Tube changes and Repositioning
0122	Level II Tube changes and Repositioning
0140	Esophageal Dilation without Endoscopy

Proposed Rule APC	Description
0146	Level I Sigmoidoscopy
0147	Level II Sigmoidoscopy
0148	Level I Anal/Rectal Procedure
0164	Level I Urinary and Anal Procedures
0183	Testes/Epididymis Procedures
0187	Miscellaneous Placement/Repositioning
0204	Level I Nerve Injections
0212	Nervous System Injections
0213	Extended EEG Studies and Sleep Studies, Level I
0214	Electroencephalogram
0230	Level I Eye Tests and Treatments
0235	Level I Posterior Segment Eye Procedures
0236	Level II Posterior Segment
0251	Level I ENT Procedures
0252	Level II ENT Procedures
0262	Plain Film of Teeth
0268	Ultrasound Guidance Procedures
0274	Myelography
0281	Venography of Extremity
0285	Myocardial Positron Emission Tomography
0297	Level II Therapeutic Radiologic Procedures
0303	Treatment Device Construction
0322	Brief Individual Psychotherapy
0335	Magnetic Resonance Imaging, Miscellaneous
0340	Minor Ancillary Procedures
0341	Skin Tests
0344	Level III Pathology
0355	Level I Immunizations
0356	Level II Immunizations
0364	Level I Audiometry
0370	Allergy Tests
0373	Neuropsychological Testing
0397	Vascular Imaging
0407	Radionuclide Therapy
0409	Red Blood Cell Tests
0422	Level II Upper GI Procedures
0600	Low Level Clinic Visits
0688	Revision/Removal Neurostimulator Pulse Generator Receiver
0692	Electronic Analysis of Neurostimulator Pulse Generators
0699	Level IV Eye Tests & Treatments

E. Coding for Stereotactic Radiosurgery Services

[If you choose to comment on issues in this section please indicate the caption "Stereotactic Radiosurgery" at the beginning of your comment.]

1. Background

In the November 7, 2003 final rule with comment period (68 FR 63403), we discussed the APC Panel's consideration

of HCPCS codes G0242 (Cobalt 60-based stereotactic radiosurgery plan) and G0243 (Cobalt 60-based stereotactic radiosurgery delivery). At its August 22, 2003 meeting, the APC Panel discussed combining the coding for these procedures under one code, with the payment for the new code derived by adding the payment for HCPCS codes G0242 and G0243 together. The APC Panel recommended that we solicit additional input from professional societies representing neurosurgeons, radiation oncologists, and other experts in the field before recommending changes to the coding configuration for Cobalt 60-based stereotactic radiosurgery planning and delivery.

In a correction to the November 7, 2003 final rule with comment period, issued on December 31, 2003 (68 FR 75442), we considered a commenter's request to combine HCPCS codes G0242 and G0243 into a single procedure code in order to accurately capture the costs of this treatment in a single procedure claim because the majority of patients receive the planning and delivery of this treatment on the same day. We responded to the commenter's request by explaining that several other commenters stated that HCPCS code G0242 was being misused to code for the planning phase of linear accelerator-based stereotactic radiosurgery planning. Because the claims data for HCPCS code G0242 represent costs for linear accelerator-based stereotactic radiosurgery planning (due to misuse of the code), in addition to Cobalt 60-based stereotactic radiosurgery planning, we were uncertain as to how to combine these data with HCPCS code G0243 to determine an accurate payment rate for a combined code for planning and delivery of Cobalt 60-based stereotactic radiosurgery.

In consideration of the misuse of HCPCS code G0242 and the potential for causing greater confusion by combining codes G0242 and G0243, we created a planning code for linear accelerator-based stereotactic radiosurgery (G0338) to distinguish this procedure from Cobalt 60-based stereotactic radiosurgery planning. We maintained both HCPCS codes G0242 and G0243 for the planning and delivery of Cobalt 60-based stereotactic radiosurgery treatment, consistent with the use of two G codes for planning (G0338) and delivery (G0173, G0251, G0339, G0340, as applicable) of each type of linear accelerator-based treatment. We indicated that we intend to maintain these new codes in their current new technology APCs until the payment rates could be set using medians from this expanded set of codes. We also stated that we would solicit input from the APC Panel at its February 2004 meeting.

During the February 2004 APC Panel meeting, several presenters discussed with the APC Panel their rationale for requesting that HCPCS codes G0242 and G0243 be combined into a single procedure code. One presenter explained that the request to combine the codes was made because certain fiscal intermediaries were rejecting claims in which HCPCS codes G0242 and G0243 were reported with a surgery revenue code. Although we have not issued any national instructions to fiscal intermediaries to deny claims for these services if they are billed with a surgery revenue code, the presenter stated that we may have indirectly led some fiscal intermediaries to believe that Cobalt 60-based stereotactic radiosurgery should be reported with a radiation therapy revenue center because the procedure is separated into a planning code and a delivery code, which reflect the coding pattern of a radiation therapy procedure rather than a single code for a surgical procedure. The presenter stated that because of the way that CMS has coded this procedure, some fiscal intermediaries have established local edits to deny claims in which HCPCS codes G0242 and G0243 are reported on a claim with a surgery revenue code.

The APC Panel recommended that CMS work with the presenters to determine if any fiscal intermediaries have established local edits to reject claims in which HCPCS codes G0242 and G0243 are reported on a claim, and to determine specific reasons for any such local edits. The APC Panel also recommended that CMS take necessary action to ensure that any such claims are not being denied payment due to local edits. The APC Panel did not agree that the solution to ensuring payment was to combine HCPCS codes G0242 and G0243 into a single code, but rather recommended that CMS educate fiscal intermediaries as to the appropriate procedures for submittal of these claims for Medicare payment.

In response to the concern expressed by several presenters that certain fiscal intermediaries were rejecting claims in which HCPCS codes G0242 and G0243 were reported with a surgery revenue code, we have worked together with these presenters to identify specific fiscal intermediaries who may be rejecting these claims. However, to date, we have been unable to identify any fiscal intermediaries who have established local edits that would reject claims in which HCPCS codes G0242 and G0243 are reported with a surgery revenue code. If a provider should experience a rejection of such claims in which HCPCS codes G0242 and G0243 are reported on a claim with a surgery revenue code, they should contact their fiscal intermediary to determine the specific reason for the claim rejection.

2. Proposal for CY 2005

For CY 2005, we are proposing to accept the APC Panel's recommendation to work with the presenters to ensure that claims in which HCPCS codes G0242 and G0243 are reported are not being unjustly denied payment due to local edits established by fiscal intermediaries. In the meantime, for CY 2005, we are proposing to maintain HCPCS code G0242 in new technology APC 1516 at a payment rate of $1,450, and HCPCS code G0243 in new technology APC 1528 at a payment rate of $5,250. These payment rates are the same as those established for CY 2004.

F. Proposed Movement of Procedures From New Technology APCs to Clinically Appropriate APCs

[If you choose to comment on issues in this section, please indicate the caption "New Technology APCs'' at the beginning of your comment.]

1. Background

In the November 30, 2001 final rule (66 FR 59903), we made final our proposal to change the period of time during which a service may be paid under a new technology APC. The April 7, 2000 final rule initially established the timeframe that new technology APCs would be in effect (65 FR 18457). Beginning in CY 2002, we have retained services within new technology APC groups until we have acquired adequate data that allow 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, and it also allows us to retain a service in a new technology APC for more than 3 years if sufficient data upon which to base a decision for reassignment have not been collected.

In the November 7, 2003 final rule with comment period we implemented a comprehensive restructuring of the new technology APCs to make the payment levels more consistent (68 FR 63416). We established payment levels in $50, $100, and $500 intervals and expanded the number of new technology payment levels.

2. APC Panel Review and Recommendation

During the APC Panel's February 2004 meeting, the APC Panel heard testimony from several interested parties who

requested specific modifications to the APCs for radiation oncology APC. They asked the APC Panel to make several recommendations: (1) That we move CPT code 77418 (Intensity-modulated radiation therapy) from APC 0412 back into a new technology APC; (2) that we dampen, or limit, any possible payment reductions to APC 0301 (Level II Radiation Therapy); (3) that we accept more external data to evaluate costs; and (4) that we identify more claims that are useful for ratesetting.

In response to the testimony presented, the APC Panel recommended that we reassign CPT code 77418 to the new technology APC 1510 for CY 2005 and that we explain to providers any steps we take to limit payment reductions to APC 0301 so that they can better plan for future years during which we may decide not to apply a dampening, or payment reduction limitation, to the rates for APC 0301.

We are not proposing to accept the APC Panel's recommendations because we believe that we have ample claims data for use in determining an appropriate APC payment rate for CPT code 77418. Moreover, we believe that the development of median cost for CPT code 77418 based on those data would be representative of hospital bills.

We have over 255,000 claims for this service, and over 95 percent were single claims that we could use for ratesetting. Moreover, the APC medians have been stable for the last 2 years of data. As indicated by our claims data, returning code 77418 to new technology APC 1510 would result in a payment for the service that is significantly higher than the resources utilized to provide it.

3. Proposal for CY 2005

There are 24 procedures currently assigned to new technology APCs for which we have data adequate to support assignment into clinical APCs. We are proposing to reassign these procedures to clinically appropriate APCs. We are proposing to assign 24 of the procedures to clinically appropriate APCs using CY 2003 claims data to set medians on which payments would be based. These APCs and the proposed assignments are displayed below in Table 14.

Based upon our review of the latest claims data available, we are proposing to move the procedures listed in Table 14 from their current new technology APCs to the APCs listed, as we have adequate data on these procedures to enable us to make the necessary APC assignment.

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Table 14.--Proposed APC Reassignment of New Technology Procedures Into Clinical APCs

HCPCS	Descriptor	CY 2004 APC	Proposed CY 2005 APC	CY 2004 Payment Amount	Proposed CY 2005 Payment Amount
15860	Test for blood flow in graft	1501	0359	$25.00	$49.93
96003	Dynamic fine wire EMG	1503	0215	$150.00	$38.00
96000	Motion analyses, video/3D	1503	0216	$150.00	$150.51
96001	Motion test w/ft pressure measure	1503	0216	$150.00	$150.51
96002	Dynamic surface EMG	1503	0218	$150.00	$65.90
91110	GI tract capsule endoscopy	1508	0141	$650.00	$464.52
G0288	Reconstruction, CTA surgical plan	1506	0417	$450.00	$246.99
G0262	Small intestinal image capsule	1508	0141	$650.00	$464.52
77301	Radiotherapy dose plan, IMRT	1510	0310	$850.00	$811.91
77523	Proton treatment, intermediate	1511	0419	$950.00	$678.31
77525	Proton treatment, complex	1511	0419	$950.00	$678.31
95250	Glucose monitoring, continuous	1540	0421	$150.00	$103.89
96567	Photodynamic treatment, skin	1540	0013	$150.00	$66.15
96570	Photodynamic treatment, 30 min.	1541	0015	$250.00	$99.24
96571	Photodynamic treatment, 15 min.	1541	0012	$250.00	$43.16
92973	Perc. Coronary thrombectomy	1541	0676	$250.00	$245.74
36595	Mech remov tunneled CV Cath	1541	0187	$250.00	$219.45
36596	Mech remov tunneled CV Cath	1541	0187	$250.00	$219.45
33224	Insert pacing lead and	1547	0418	$850.00	$4,456.64

HCPCS	Descriptor	CY 2004 APC	Proposed CY 2005 APC	CY 2004 Payment Amount	Proposed CY 2005 Payment Amount
	connect				
33225	L ventricular pacing lead add-on	1550	1525	$1,150.00	$3,750.00
53853	Prostatic water thermometer	1550	0162	$1,150.00	$1,323.06
47382	Perc. ablation liver tumor, rf	1557	0423	$1,850.00	$1,659.71
0009T	Endometrial cryoablation	1557	0202	$1,850.00	$2,281.74
C9703	Bard Endoscopic Suturing Sys	1518	0422	$1650.00	$1274.51
C9701	Stretta System	1520	0422	$1650.00	$1274.51

We believe the payment rates in Table 14 for several of the procedures that we are proposing to move out of new technology APCs and into clinical APCs require further explanation for a fuller understanding.

For CPT code 96567, (Photodynamic therapy of the skin), the impact of the estimated payment decrease between CY 2004 and CY 2005 is actually low as the CY 2004 payment included the topically applied drug required to perform this procedure and the CY 2005 estimated payment does not. We now are proposing to pay separately for the drug billed under code J7308 in CY 2005. We have adequate claims data on which to base payment for that procedure in a clinically appropriate APC. Payment based on those data in addition to removal of the drug for separate payment resulted in a lower median for the APC.

In the case of CPT code 33224, (Insertion of a left ventricular pacing lead and connection), based on a comparison of payment rates for CY 2004 and the estimated rate for CY 2005, it appears that there is a large increase in payment that results from reassigning the code from its new technology APC to a clinical APC. The difference is due to the fact that the estimated CY 2005 APC payment includes the cost of the left ventricular lead that was not included in the CY 2004 new technology APC payment. That left ventricular lead was paid as a pass-through device under code C1900 in CY 2004, but is no longer eligible for pass-through payments in CY 2005, and, as such, is now included in the APC for the procedure.

Similarly, the CY 2005 estimated payment for CPT code 33225, (Left ventricular pacing lead add-on), includes the cost of the ventricular lead. However, for 33225, the data are still somewhat unstable. Therefore, we are proposing to maintain that procedure in a new technology APC, but at a higher payment level, reflecting the additional cost of the lead.

We note that a number of positron emission tomography (PET) scans currently are classified into New Technology APC 1516. We recognize that PET is an important technology in many instances and want to ensure that the technology remains available to Medicare beneficiaries when medically necessary. We believe that we have sufficient data to assign PET scans to a clinically appropriate APC. We have been told, however, that if the effect of doing so is to reduce payment for the procedure, it may hinder access to this technology. Therefore, we are considering three options as the proposed payment for these procedures in CY 2005, based on our review of the 2003 claims data for the PET procedures, and we specifically invite comments on each of these options.

Option 1: Continue in CY 2005 the current assignment of the scans to New Technology APC 1516 prior to assigning to a clinical APC.

Option 2: Assign the PET scans to a clinically appropriate APC priced according to the median cost of the scans based on CY 2003 claims data. Under this option, we would assign PET scans to APC 0420, PET imaging.

Option 3: Transition assignment to a clinical APC in CY 2006 by setting payment in CY 2005 based on a 50–50 blend of the median cost and the CY 2004 New Technology. We would assign the scans to New Technology APC 1513 for a blended transition payment. The rates for these options are in addendum B.

G. Proposed Changes to the Inpatient List

[If you choose to comment on issues in this section, please indicate the caption ''Inpatient List'' at the beginning of your comment.]

We advised the APC Panel of a request that we had received to move four codes for percutaneous abscess drainage 44901(Drain append. abscess, percutaneous), 49021 (Drain abdominal abscess), 49041 (Drain percutaneous abdominal abscess), 49061(Drain, percutaneous, retroper. abscess)) from the inpatient list and to assign them to appropriate APCs. The APC Panel also recommended that we evaluate other codes on the inpatient list for possible APC assignment and that we consider eliminating the inpatient list.

We are proposing to remove the four above-cited codes and assign them to clinically appropriate APCs, as recommended by the APC Panel. We are proposing to assign code 44901 to APC 0037, code 49021 to APC 0037; code 49041 to APC 0037; and code 49061 to APC 0037. We discuss in section VII.E. of this preamble our response to the APC Panel's recommendation that we either abolish the inpatient list or evaluate it for any appropriate changes.

H. Proposed Assignment of ''Unlisted'' HCPCS Codes

[If you choose to comment on issues in this section, please indicate the caption

"Unlisted HCPCS Codes'' at the beginning of your comment.]

1. Background

Some HCPCS codes are used to report services that do not have descriptors that define the exact service furnished. They are commonly called "unlisted'' codes. The code descriptors often contain phrases such as: "unlisted procedure'', "not otherwise classified,'' or "not otherwise specified.'' The unlisted codes typically fall within a clinical or procedural category, but they lack the specificity needed to describe the resources used in the service. For example, CPT code 17999 is defined as, "Unlisted procedure, skin, mucous membrane and subcutaneous tissue.'' The unlisted codes provide a way for providers to report services for which there is no HCPCS code that specifically describes the service furnished. However, the lack of specificity in describing the service prevents us from assigning the code to an APC based on clinical homogeneity and median cost.

In most cases, the unlisted codes are assigned to the lowest level, clinically appropriate APC under the Medicare OPPS. This creates an incentive for providers to select the appropriate, specific HCPCS code to describe the service where one is available. In addition, if there is no HCPCS code that accurately describes the service, placing the unlisted code in the lowest level APC provides an incentive for interested parties to secure a code through the AMA's CPT process that will describe the service. Once a code that accurately describes the service is created, we can collect data on the service and place it in the correct APC based on the clinical nature of the service and its median cost.

We do not use the median cost for the unlisted codes in the establishment of the weight for the APC to which the code is assigned because, by definition of the code, we do not know what service or combination of services is reflected in the claims billed using the unlisted code.

Our review of HCPCS code assignments to APCs has revealed that there are a number of unlisted codes that are not assigned to the lowest level APC.

2. Proposal for CY 2005

We are proposing to reassign these unlisted codes for CY 2005 OPPS to the lowest level APC in the clinical grouping in which the unlisted code is located. The list of those codes, the current APC assignment, and the assignment we propose for CY 2005 OPPS are displayed in Table 15.

We continue to believe that assigning unlisted codes to the lowest level of the APC for the clinical or procedural grouping into which the code falls creates an appropriate incentive for providers to pursue assignment of new codes where they are needed. Moreover, payment at the lowest level of APC for the clinical or procedural grouping allows for some payment for the services furnished and also ensures that we do not pay inappropriately for services that are unspecified.

Table 15.--Proposed Reassignments of Unlisted HCPCS Codes

HCPCS Short Description	CY 2004 APC Assignment	Proposed CY 2005 APC
15999	0022	0019
21089	0253	0251
21299	0253	0251
21499	0253	0251
21899	0252	0251
22999	0022	0019
31299	0252	0251
31599	0254	0251
40799	0253	0251
40899	0252	0251
41899	0253	0251
42699	0253	0251
42999	0252	0251
47399	0037	0002
48999	0005	0004
49659	0131	0130
67599	0239	0238
67999	0240	0238
68399	0239	0238
68899	0699	0230
69799	0253	0251
69949	0253	0251

I. Proposed Addition of New Procedure Codes

During the first two quarters of CY 2004, we created 85 HCPCS codes that were not addressed in the November 7, 2003 final rule that updated the CY 2004 OPPS. We have designated the payment status of those codes, which are shown in Table 16 below, and added them to the April and July updates of the 2004 OPPS (Transmittals 3144, 3154, 3322, and 3324). Thirty of the new codes were created to enable providers to bill for brand name drugs and to receive payments at a rate that differs from that for generic equivalents, as mandated in new section 1833(t)(14)(A)(i) of the Act as added by Pub. L. 108–173. In this proposed rule, we are soliciting comment on the APC assignment of these services. Further, consistent with our annual APC updating policy, we are proposing to assign the new HCPCS codes for CY 2005 to the appropriate APCs and would incorporate them into our final rule for CY 2005.

Table 16.--New HCPCS Codes Implemented in April and July 2004

CPT/ HCPCS	Description
C9213	Injection, Pemetrexed
C9214	Injection, Bevacizumab
C9215	Injection, Cetuximab
C9216	Abarelix, Inject Suspension
C9217	Injection, Omalizumab
C9399	Unclassified drugs or biologicals
C9400	Thallous chloride, brand
C9401	Strontium-89 chloride, brand
C9402	Th I131 so iodide cap, brand
C9403	Dx I131 so iodide cap, brand
C9404	Dx I131 so iodide sol, brand
C9405	Th I131 so iodide sol, brand
C9410	Dexrazoxane HCl inj, brand
C9411	Pamidronate disodium, brand
C9412	Ganciclovir implant, brand
C9413	Sodium hyaluronate inj, brand
C9414	Etoposide oral, brand
C9415	Doxorubic hcl chemo, brand
C9417	Bleomycin sulfate inj, brand
C9418	Cisplatin inj, brand
C9419	Inj cladribine, brand
C9420	Cyclophosphamide inj, brand
C9421	Cyclophosphamide lyo, brand
C9422	Cytarabine hcl inj, brand
C9423	Dacarbazine inj, brand
C9424	Daunorubicin, brand
C9425	Etoposide inj, brand
C9426	Floxuridine inj, brand
C9427	Ifosfomide inj, brand
C9428	Mesna injection, brand
C9429	Idarubicin hcl inj, brand
C9430	Leuprolide acetate inj, bran
C9431	Paclitaxel inj, brand
C9432	Mitomycin inj, brand
C9433	Thiotepa inj, brand

CPT/ HCPCS	Description
C9438	Cyclosporine oral, brand
C9712	Insert pH capsule, GERD
C9713	Non-contact laser vap prosta
C9714	Breast inters rad tx, immed
C9715	Breast inters rad tx, delay
C9716	RF Energy to Anus
G0329	Electromagntic tx for ulcers
K0627	Cervical pneum trac equip
K0628	Mult dens insert direct form
K0629	Mult dens insert custom mold
K0630	SIO flex pelvisacral prefab
K0631	SIO flex pelvisacral custom
K0632	SIO panel prefab
K0633	SIO panel custom
K0634	LO flexibl L1 - below L5 pre
K0635	LO sag stays/panels pre-fab
K0636	LO sagitt rigid panel prefab
K0637	LO flex w/o rigid stays pre
K0638	LSO flex w/rigid stays cust
K0639	LSO post rigid panel pre
K0640	LSO sag-coro rigid frame pre
K0641	LSO sag-cor rigid frame cust
K0642	LSO flexion control prefab
K0643	LSO flexion control custom
K0644	LSO sagit rigid panel prefab
K0645	LSO sagittal rigid panel cus
K0646	LSO sag-coronal panel prefab
K0647	LSO sag-coronal panel custom
K0648	LSO s/c shell/panel prefab
K0649	LSO s/c shell/panel custom
K0650	Gen w/c cushion width <22"
K0651	Gen w/c cushion width >=22"
K0652	Skin protect w/c cus wd <22"
K0653	Skin protect w/c cus wd >=22"
K0654	Position w/c cush width <22"
K0655	Position w/c cush width >=22"
K0656	Skin pro/pos w/c cus wd<22"
K0657	Skin pro/pos w/c cus wd >=22"
K0658	Custom fabricate w/c cushion
K0659	Powered w/c cushion
K0660	Gen use back cush width <22"
K0661	Gen use back cush width >=22"
K0662	Position back cush wdth <22"
K0663	Position back cush wdth >=22"
K0664	Pos back post/lat width <22"
K0665	Pos back post/lat width >=22"
K0666	Custom fab w/c back cushion
K0667	Mt hardwre man/light pwr w/c
K0668	Rep ace cover w/c seat cush
K0669	W/c seat/back no CVR SADMERC

J. Proposed OPPS Changes: Provisions of MMA (Pub. L. 108–173)

1. Payment for Initial Preventive Physical Examinations (Section 611 of Pub. L. 108–173)

[If you choose to comment on issues in this section, please indicate the caption ''Physical Examinations'' at the beginning of your comment.]

a. Background

Section 611 of Pub. 108–173 provides for coverage under Medicare Part B of an initial preventive physical examination for new beneficiaries, effective for services furnished on or after January 1, 2005. This provision applies to beneficiaries whose coverage period under Medicare Part B begins on or after January 1, 2005, and only for an initial preventive physical examination performed within 6 months of the beneficiary's initial coverage date.

Current Medicare coverage policy does not allow for payment for routine physical examinations (or checkups) that are furnished to beneficiaries. Before the enactment of Pub. L. 108–173, all preventive physical examinations had been excluded from coverage based on section 1862(a)(7) of the Act, which states that routine physical checkups are excluded services. This exclusion is specified in regulations under § 411.15(a). In addition, preventive physical examinations had been excluded from coverage based on section 1862(a)(1)(A) of the Act. This section of the Act provides that items and services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (as implemented in regulations under § 411.15(k)).

Coverage of initial preventive physical examinations is provided only under Medicare Part B. As provided in the statute, this new coverage allows payment for one initial preventive physical examination within the first 6 months after the beneficiary's first Part B coverage begins, although that coverage period may not begin before January 1, 2005. We also note that Pub. L. 108–173 did not make any provision for the waiver of the Medicare coinsurance and Part B deductible for the initial preventive physical examination. Payment for this service would be applied to the required Medicare Part B deductible, which is $110 for CY 2005, if the deductible has not been met, and the usual coinsurance provisions would apply.

b. Proposed Amendments to Regulations

We are proposing to amend our regulations to add a new § 410.16 that would provide for coverage of initial preventive physical examinations in various settings, including the hospital outpatient department, as specified in the statute, and specify the condition for coverage and limitation on coverage. In addition, we are proposing to conform our regulations on exclusions from coverage under § 411.15(a)(1) and § 411.15(k) to the provisions of section 611 of Pub. L. 108–173. Specifically, we are proposing to specify an exception to the list of examples of routine physical checkups that are excluded from coverage under § 411.15(a) and to add a new exclusion under § 411.15(k)(11).

We are proposing to amend § 419.21 of the OPPS regulations to add a new paragraph (e) to specify payment for an initial preventive physical examination as a Medicare Part B covered service under the OPPS if the examination is furnished within the first 6 months of the beneficiary's first Medicare Part B coverage.

We note that the initial preventive physical examination is also addressed in detail in our proposed rule to update the Medicare Physician's Fee Schedule for CY 2005. However, because we believe the same elements of the initial physical examination furnished in a physician's office would also apply when the examination is performed in a hospital outpatient clinic, we are proposing to revise the applicable regulations to reflect this requirement.

Section of 611(b) of Pub. L. 1089–173 define an ''initial preventive physical examination'' to mean physicians'' services consisting of—

(1) A physical examination (including measurement of height, weight, blood pressure, and an electrocardiogram, but excluding clinical laboratory tests) with the goal of health promotion and disease detection; and

(2) Education, counseling, and referral with respect to screening and other preventive coverage benefits separately authorized under Medicare Part B, excluding clinical lab tests.

Specifically, section 611(b) of Pub. L. 108–173 provides that the education, counseling, and referral services with respect to the screening and other preventive services authorized under Medicare Part B include the following:

(1) Pneumococcal, influenza, and hepatitis B vaccine and their administration;

(2) Screening mammography;

(3) Screening pap smear and screening pap smear and screening pelvic examination;

(4) Prostate cancer screening tests;

(5) Colorectal cancer screening tests;

(6) Diabetes outpatient self-management training services;

(7) Bone mass measurements;

(8) Screening for glaucoma;

(9) Medical nutrition therapy services for individuals with diabetes and renal disease;

(10) Cardiovascular screening blood tests; and

(11) Diabetes screening tests.

Section 611(d)(2) of Pub. L 108–173 amended section 1861(s)(2)(K)(i) and (ii) of the Act to specify the services identified as physicians' services and referred to in the definition of initial preventive physical examination include services furnished by a physician assistant, a nurse practitioner, or a clinical nurse specialist. We refer to these professionals as ''qualified nonphysician practitioners.''

Based on the language of the statute, our review of the medical literature, current clinical practice guidelines, and United States Preventive Services Task Force recommendations, we are proposing (under proposed new § 410.16(a), Definitions) to interpret the term ''initial preventive physical examination'' for purposes of this new benefit to include all of the following services furnished by a doctor of medicine or osteopathy or a qualified nonphysician practitioner:

(1) Review of the individual's comprehensive medical and social history. We are proposing to define ''medical history'' to include, as a minimum, past medical and surgical history, including experience with illnesses, hospital stays, operations, allergies, injuries, and treatments; current medications and supplements, including calcium and vitamins; and family history, including a review of medical events in the patient's family, including diseases that may be hereditary or place the individual at risk. We are proposing to define ''social history'' to include, at a minimum, history of alcohol, tobacco, and illicit drug use; work and travel history; diet; social activities; and physical activities.

(2) Review of the individual's potential (risk factors) for depression (including past experiences with depression or other mood disorders) based on the use of an appropriate screening instrument that the physician or other qualified nonphysician practitioner may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is defined through the national coverage determination (NCD) process.

(3) Review of the individual's functional ability and level of safety (that is, at a minimum, a review of the following areas: hearing impairment, activities of daily living, falls risk, and home safety), based on the use of an appropriate screening instrument, which the physician or other qualified nonphysician practitioner may select from various available standardized screening tests for this purpose, unless the appropriate screening instrument is further defined through the NCD process.

(4) An examination to include measurement of the individual's height, weight, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the individual's comprehensive medical and social history and current clinical standards.

(5) Performance of an electrocardiogram and interpretation.

(6) Education, counseling, and referral, as deemed appropriate, based on the results of elements (1) through (5) of the proposed definition of the initial preventive physical examination.

(7) Education, counseling, and referral, including a written plan for obtaining the appropriate screening and other preventive services, which are also covered as separate Medicare Part B benefits; that is, pnuemococcal, influenza, and hepatitis B vaccines and their administration, screening mammography, screening pap smear and screening pelvic exams, prostate cancer screening tests, diabetes outpatient self-management training services, bone mass measurements, screening for glaucoma, medical nutrition therapy services, cardiovascular screening blood tests, and diabetes screening tests.

In view of the possibility that it may be appropriate to include other (or revised) elements in the definition of the term "initial preventive physical examination,'' we are requesting public comments on this issue. For example, we have chosen not to define the term "appropriate screening instrument'' for screening individuals for depression, alcohol, tobacco and illicit drug use, functional ability, and level of safety because we anticipate that the examining physician or qualified nonphysician practitioner would want to use the test of his or her choice, based on current clinical practice guidelines. We believe that any standardized screening test for depression, substance abuse, functional ability, and level of safety recognized by the American Academy of Family Physicians, the American College of Physicians-American Society of Internal Medical, the American College of Preventive Medicine, the American Geriatrics Society, the American Psychiatric Association, and the United States Preventive Services Task Force would be acceptable for purposes of meeting the "appropriate screening instrument'' provision.

To facilitate our future consideration of defining more specifically the type or types of appropriate screening instruments for depression, substance abuse, functional ability, or level of safety, we are proposing to include provisions in paragraphs (2) and (3) under the proposed definition of initial preventive physical examination that would allow us to do this through the NCD process. This proposed approach would allow us to conduct a more timely assessment of new types of screening tests than would be possible under the standard rulemaking process. We intend to use the NCD process, if necessary, for evaluating appropriate new screening tests for depression; alcohol, tobacco and illicit drug use; functional ability; or level of safety. This NCD process includes an opportunity for public comment in order to evaluate the medical and scientific issues related to the coverage of the new tests that may be brought to our attention in the future.

c. Proposed Assignment of New HCPCS Code for Payment of Initial Preventive Physical Examinations

There is no current CPT code that contains the specific elements included in the initial preventive physical examination. Therefore, we are proposing to establish the following new HCPCS code, GXXXX, Initial preventive physical examination, to be used to bill for the new service under both the Medicare physician fee schedule and the OPPS. As required by the statute, this code includes an electrocardiogram, but does not include the other previously mentioned preventive services that are currently separately covered and paid under the Medicare Part B screening benefits. When these other preventive services are performed, they should be identified using the existing appropriate codes.

For payment under the physician fee schedule, relative value units are being proposed for new HCPCS code GXXXX based on equivalent resources and work intensity to those contained in CPT E/M code 99203 (new patient, office or other outpatient visit) and CPT 93000 (electrocardiogram, complete). The "technical component'' is the portion of the physician fee schedule that is most comparable to what Medicare pays under the OPPS, the costs other than the physician professional services that are billed and paid for separately under the fee schedule, not OPPS. The estimated technical component of the physician fee schedule is between $50 and $100.

Given our lack of cost data to guide assignment of the new benefit into a clinically appropriate APC, we are proposing to assign GXXXX to the new technology APC 1539 that has a payment level of $50 to $100. Temporary assignment to a new technology APC allows us to pay for the new benefit provided in the OPD while we accrue claims data and experience on which to base a clinically relevant APC assignment.

d. Handling of Comments Received in Response to This Proposal

We will respond to all comments regarding the proposed elements required for the initial preventive physical examination, whether the examination is performed in a physician's office or clinic or in a hospital clinic, in the final rule implementing the Medicare Physician Fee Schedule for CY 2005. We will respond to comments regarding payment for the examination under the OPPS in the subsequent final rule implementing the OPPS payment rates for CY 2005.

2. Payment for Certain Mammography Services (Section 614 of Pub. L. 108–173)

[If you choose to comment on issues in this section, please indicate the caption "Mammography'' at the beginning of your comment.]

Section 614 of Pub. L. 108–173 amended section 1833(t)(1)(B)(iv) of the Act to provide that screening mammography and diagnostic mammography services are excluded from payment under the OPPS. This amendment applies to screening mammography services furnished on or after December 8, 2003 (the date of the enactment of Pub. L. 108–173), and in the case of diagnostic mammography, to services furnished on or after January 1, 2005. As a result of this amendment, both screening mammography and diagnostic mammography will be paid under the physician fee schedule.

We are proposing to amend § 419.22 of the regulations by adding a new paragraph(s) to specify that both screening mammography and diagnostic mammography will be excluded from payment under the OPPS, in accordance with section 614 of Pub. L. 108–173.

III. Proposed Recalibration of APC Relative Weights for CY 2005

[If you choose to comment on issues in this section, please include the caption

"APC Relative Weights'' at the beginning of your comment.]

A. Database Construction

Section 1833(t)(9)(A) of the Act requires that the Secretary review and revise the relative payment weights for APCs at least annually, beginning in CY 2001 for application in CY 2002. In the April 7, 2000 final rule (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. Except for some reweighting due to APC changes, these relative weights continued to be in effect for CY 2001. (See the November 13, 2000 interim final rule (65 FR 67824 through 67827).)

To recalibrate the relative APC weights for services furnished on or after January 1, 2005, and before January 1, 2006, we are proposing to use the same basic methodology that we described in the April 7, 2000 final rule. That is, we would recalibrate the weights based on claims and cost report data for outpatient services. We are proposing to use the most recent available data to construct the database for calculating APC group weights. For the purpose of recalibrating APC relative weights for CY 2005, the most recent available claims data are the approximately 119 million final action claims for hospital OPD services furnished on or after January 1, 2003, and before January 1, 2004.

Of the 119 million final action claims for OPPS services, 96.7 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 OPPS). Of the 96.7 million claims, we were able to use 48.5 million whole claims (from which we created 75 million single procedure claim records) to set OPPS proposed for CY 2005 weights.

The proposed weights and payments in Addenda A and B to this proposed rule were calculated using claims from this period that had been processed before January 1, 2004. 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 are proposing that the APC relative weights for CY 2005 under the OPPS would continue to be based on the median hospital costs for services in the APC groups. For the final rule, we are proposing to base median costs on claims for services furnished in CY 2003 and processed before June 30, 2004.

1. Proposed Treatment of Multiple Procedure Claims

For CY 2005, we are proposing to continue to use single procedure claims to set the medians on which the weights would be based. We have received many requests that we ensure that the data from claims that contain charges for multiple procedures are included in the data from which we calculate the CY 2005 relative payment weights. Requesters believe that relying solely on single procedure claims to recalibrate APC weights fails to take into account data for many frequently performed procedures, particularly those commonly performed in combination with other procedures. They believe that, by depending upon single procedure claims, we base payment weights on the least costly services, thereby introducing downward bias to the medians on which the weights are based.

We agree that, optimally, it is desirable to use the data from as many claims as possible to recalibrate the relative payment weights, including those with multiple procedures. As discussed in the explanation of single procedure claims below, we have used the date of service on the claims and a list of codes to be bypassed to create "pseudo'' single claims from multiple procedure claims. We refer to these newly created single procedure claims as "pseudo'' singles because they were submitted by providers as multiple procedure claims.

2. Proposed Use of Single Procedure Claims

We use single procedure claims to set the median costs for APCs because we are, so far, unable to ensure that packaged costs can be correctly allocated across multiple procedures performed on the same date of service. However, bypassing specified codes that we believe do not have significant packaged costs enables use of more data from multiple procedure claims. For CY 2003, we created "pseudo'' single claims by bypassing HCPCS codes 93005 (Electrocardiogram, tracing), 71010 (Chest x-ray), and 71020 (Chest x-ray) on a submitted claim. However, we did not use claims data for the bypassed codes in the creation of the median costs for the APCs to which these three codes were assigned because the level of packaging that would have remained on the claim after we selected the bypass code was not apparent and therefore, it was difficult to determine if the medians for these codes would be correct.

For CY 2004, we created "pseudo'' single claims by bypassing these three codes and also by bypassing an additional 269 HCPCS codes in APCs. These codes were selected by CMS based on a clinical review of the services and because it was presumed that these codes had only very limited packaging and could appropriately be bypassed for the purpose of creating "pseudo'' single claims. The APCs to which these codes were assigned were varied and included mammography, cardiac rehabilitation, and level I plain film x-rays. To derive more "pseudo'' single claims, we also broke claims apart where there were dates of service for revenue code charges on that claim that could be matched to a single procedure code on the claim on the same date.

As in CY 2003, we did not include the claims data for the bypassed codes in the creation of the APCs to which the 269 codes were assigned because, again, we had not established that such an approach was appropriate and would aid in accurately estimating the median cost for that APC. For CY 2004, from about 16.3 million otherwise unusable claims, we were able to use about 9.5 million multiple procedure claims to create about 27 million "pseudo'' single claims. For CY 2005, from about 21 million otherwise unusable claims, we were able to use about 18 million multiple procedure claims to create about 45.5 million "pseudo'' single claims.

For CY 2005, we are proposing to continue using date of service matching as a tool for creation of "pseudo'' single claims and also to take a more empirical approach to creating the list of codes that we would bypass to create "pseudo'' single claims. The process we are proposing for CY 2005 OPPS results in our being able to use some part of 93 percent of the total claims eligible for use in OPPS ratesetting and modeling. In CY 2004, we were able to use some part of the data from 82 percent of eligible claims. This process enabled us to use 75 million single bills for ratesetting: 45.5 million "pseudo'' singles and 30.5 million "natural'' single bills.

We are proposing to bypass the 383 codes identified in Table 17 to create new single claims and to use the line-item costs associated with the bypass codes on these claims in the creation of the median costs for the APCs into which they are assigned. Of the codes on this list, only 123 (32 percent) were used for bypass in CY 2004.

We developed the proposed bypass list using four criteria:

a. We developed the following empirical standards by reviewing the frequency and magnitude of packaging in the single claims for payable codes other than drugs and biologicals. We assumed that the representation of packaging on the single claims for any given code is comparable to packaging for that code in the multiple claims.

- There were 100 or more single claims for the code. This ensured that observed outcomes were sufficiently representative of packaging that might occur in the multiple claims.
- Five percent or fewer of the single claims for the code had packaged costs on that single claim for the code. This criterion results in limiting the amount of packaging being redistributed to the 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. For the remaining payable codes, the average percentage of single claims with any packaged costs was 70 percent, and the chosen threshold of 5 percent fell at roughly the 15th percentile.
- The median cost of packaging observed in the single claim was 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.

b. We examined APCs relying on a low volume of single claims, and it became apparent that several radiological supervision and interpretation codes were commonly billed with the procedural codes in the APCs. We then reviewed all radiological supervision and interpretation codes to assess their viability as bypass codes. For the codes included on the list in Table 17, we determined that, generally, the packaging on claims, including these radiological supervision and interpretation codes, should be associated with the procedure performed.

c. We examined radiation planning and related codes provided by a professional organization. In the organization's opinion, the codes could safely be bypassed and used without packaging to set medians for the APCs into which these codes are assigned. Many of the codes the organization recommended met our criterion under item a., and the remaining codes were close. Therefore, after reviewing such codes, we are proposing to adopt as bypass codes all radiation planning and related codes as provided by the organization.

d. We included HCPCS codes 93005 and 71010. These codes have been bypassed for the past 3 years and generate a significant amount of new single claims because they are very commonly done on the same date of surgery. They have low median packaged costs and a low percentage of single claims with any packaged costs, 6 percent and 18 percent, respectively.

We invite public comment on the "pseudo'' single process, including the bypass list and the criteria.

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Table 17.—Proposed HCPCS Bypass Codes for Creating "Pseudo" Single Claims for Calculating Median Costs

HCPCS Code	Short Description
11719	Trim nail(s)
11720	Debride nail, 1-5
11721	Debride nail, 6 or more
31579	Diagnostic laryngoscopy
54240	Penis study
70100	X-ray exam of jaw
70110	X-ray exam of jaw
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
70355	Panoramic x-ray of jaws
70360	X-ray exam of neck
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
70544	Mr angiography head w/o dye
71015	Chest x-ray
71020	Chest x-ray
71021	Chest x-ray
71022	Chest x-ray
71030	Chest x-ray
71034	Chest x-ray and fluoroscopy
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

HCPCS Code	Short Description
71120	X-ray exam of breastbone
71130	X-ray exam of breastbone
71250	Ct thorax w/o dye
72040	X-ray exam of neck spine
72050	X-ray exam of neck spine
72052	X-ray exam of neck 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
72120	X-ray exam of lower spine
72125	Ct neck 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
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)
73218	Mri upper extremity w/o dye

HCPCS Code	Short Description
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
73721	Mri jnt of lwr extre w/o dye
74000	X-ray exam of abdomen
74210	Contrst x-ray exam of throat
74220	Contrast x-ray, esophagus
74230	Cine/vid x-ray, throat/esoph
74240	X-ray exam, upper gi tract
74245	X-ray exam, upper gi tract
74246	Contrst x-ray uppr gi tract
74247	Contrst x-ray uppr gi tract
74249	Contrst x-ray uppr gi tract
74250	X-ray exam of small bowel
76040	X-rays, bone evaluation
76061	X-rays, bone survey
76062	X-rays, bone survey
76066	Joint survey, single view
76075	Dexa, axial skeleton study
76076	Dexa, peripheral study
76078	Radiographic absorptiometry
76090	Mammogram, one breast
76091	Mammogram, both breasts
76100	X-ray exam of body section

HCPCS Code	Short Description
76101	Complex body section x-ray
76380	CAT scan follow-up study
76511	Echo exam of eye
76512	Echo exam of eye
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
76830	Transvaginal us, non-ob
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76870	Us exam, scrotum
76880	Us exam, extremity
76977	Us bone density measure
77280	Set radiation therapy field
77285	Set radiation therapy field
77300	Radiation therapy dose plan
77301	Radiotherapy dose plan, imrt
77315	Teletx isodose plan complex
77326	Brachytx isodose calc simp
77328	Brachytx isodose plan compl
77332	Radiation treatment aid(s)
77334	Radiation treatment aid(s)
77336	Radiation physics consult
77403	Radiation treatment delivery
77409	Radiation treatment delivery
77411	Radiation treatment delivery
77412	Radiation treatment delivery
77413	Radiation treatment delivery
77414	Radiation treatment delivery
77416	Radiation treatment delivery
77417	Radiology port film(s)
77418	Radiation tx delivery, imrt
78350	Bone mineral, single photon

HCPCS Code	Short Description
78351	Bone mineral, dual photon
80502	Lab pathology consultation
85060	Blood smear interpretation
86585	TB tine test
86850	RBC antibody screen
86870	RBC antibody identification
86880	Coombs test, direct
86885	Coombs test, indirect, qual
86886	Coombs test, indirect, titer
86890	Autologous blood process
86900	Blood typing, ABO
86901	Blood typing, Rh (D)
86905	Blood typing, RBC antigens
86906	Blood typing, Rh phenotype
86930	Frozen blood prep
86970	RBC pretreatment
88104	Cytopathology, fluids
88106	Cytopathology, fluids
88107	Cytopathology, fluids
88108	Cytopath, concentrate tech
88160	Cytopath smear, other source
88161	Cytopath smear, other source
88172	Cytopathology eval of fna
88180	Cell marker study
88182	Cell marker study
88300	Surgical path, gross
88304	Tissue exam by pathologist
88305	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

HCPCS Code	Short Description
90801	Psy dx interview
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
90818	Psytx, hosp, 45-50 min
90826	Intac psytx, hosp, 45-50 min
90845	Psychoanalysis
90846	Family psytx w/o patient
90847	Family psytx w/patient
90853	Group psychotherapy
90857	Intac group psytx
90862	Medication management
92002	Eye exam, new patient
92004	Eye exam, new patient
92012	Eye exam established pat
92014	Eye exam & treatment
92082	Visual field examination(s)
92083	Visual field examination(s)
92135	Opthalmic dx imaging
92136	Ophthalmic biometry
92225	Special eye exam, initial
92226	Special eye exam, subsequent
92230	Eye exam with photos
92250	Eye exam with photos
92275	Electroretinography
92285	Eye photography
92286	Internal eye photography
92520	Laryngeal function studies
92546	Sinusoidal rotational test
92548	Posturography
92552	Pure tone audiometry, air
92553	Audiometry, air & bone
92555	Speech threshold audiometry
92556	Speech audiometry, complete
92567	Tympanometry

HCPCS Code	Short Description
92582	Conditioning play audiometry
92585	Auditor evoke potent, compre
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
93278	ECG/signal-averaged
93303	Echo transthoracic
93307	Echo exam of heart
93320	Doppler echo exam, heart
93731	Analyze pacemaker system
93733	Telephone analy, pacemaker
93734	Analyze pacemaker system
93736	Telephonic analy, pacemaker
93743	Analyze ht pace device dual
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
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

HCPCS Code	Short Description
94015	Patient recorded spirometry
95115	Immunotherapy, one injection
95165	Antigen therapy services
95805	Multiple sleep latency test
95807	Sleep study, attended
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
95864	Muscle test, 4 limbs
95872	Muscle test, one fiber
95900	Motor nerve conduction test
95921	Autonomic nerv function test
95926	Somatosensory testing
95930	Visual evoked potential test
95937	Neuromuscular junction test
95950	Ambulatory eeg monitoring
95953	EEG monitoring/computer
96000	Motion analysis, video/3d
96100	Psychological testing
96105	Assessment of aphasia
96115	Neurobehavior status exam
96900	Ultraviolet light therapy
96910	Photochemotherapy with UV-B
96912	Photochemotherapy with UV-A
96913	Photochemotherapy, UV-A or B
98940	Chiropractic manipulation
99213	Office/outpatient visit, est
99214	Office/outpatient visit, est
99241	Office consultation
99243	Office consultation
99244	Office consultation
99245	Office consultation
99273	Confirmatory consultation
99274	Confirmatory consultation
99275	Confirmatory consultation
C9708	Preview Tx Planning Software

HCPCS Code	Short Description
D0473	Micro exam, prep & report
G0005	ECG 24 hour recording
G0006	ECG transmission & analysis
G0015	Post symptom ECG tracing
G0101	CA screen;pelvic/breast exam
G0127	Trim nail(s)
G0131	CT scan, bone density study
G0132	CT scan, bone density study
G0166	Extrnl counterpulse, per tx
G0175	OPPS Service,sched team conf
G0195	Clinicalevalswallowingfunct
G0196	Evalofswallowingwithradioopa
G0198	Patientadapation&trainforspe
G0202	Screeningmammographydigital
G0204	Diagnosticmammographydigital
G0206	Diagnosticmammographydigital
G0236	Digital film convert diag ma
Q0091	Obtaining screen pap smear
71090	X-ray & pacemaker insertion
74235	Remove esophagus obstruction
74300	X-ray bile ducts/pancreas
74301	X-rays at surgery add-on
74305	X-ray bile ducts/pancreas
74327	X-ray bile stone removal
74328	X-ray bile duct endoscopy
74329	X-ray for pancreas endoscopy
74330	X-ray bile/panc endoscopy
74340	X-ray guide for GI tube
74350	X-ray guide, stomach tube
74355	X-ray guide, intestinal tube
74360	X-ray guide, GI dilation
74363	X-ray, bile duct dilation
74475	X-ray control, cath insert
74480	X-ray control, cath insert
74485	X-ray guide, GU dilation
74742	X-ray, fallopian tube
75894	X-rays, transcath therapy
75898	Follow-up angiography

HCPCS Code	Short Description
75900	Arterial catheter exchange
75901	Remove cva device obstruct
75902	Remove cva lumen obstruct
75945	Intravascular us
75946	Intravascular us add-on
75952	Endovasc repair abdom aorta
75953	Abdom aneurysm endovas rpr
75954	Iliac aneurysm endovas rpr
75960	Transcatheter intro, stent
75961	Retrieval, broken catheter
75962	Repair arterial blockage
75964	Repair artery blockage, each
75966	Repair arterial blockage
75968	Repair artery blockage, each
75970	Vascular biopsy
75978	Repair venous blockage
75980	Contrast x-ray exam bile duct
75982	Contrast x-ray exam bile duct
75984	X-ray control catheter change
75992	Atherectomy, x-ray exam
75993	Atherectomy, x-ray exam
75994	Atherectomy, x-ray exam
75995	Atherectomy, x-ray exam
75996	Atherectomy, x-ray exam
75998	Fluoroguide for vein device
76012	Percut vertebroplasty fluor
76013	Percut vertebroplasty, ct
76095	Stereotactic breast biopsy
76096	X-ray of needle wire, breast
76360	Ct scan for needle biopsy
76393	Mr guidance for needle place
76941	Echo guide for transfusion
76945	Echo guide, villus sampling
76946	Echo guide for amniocentesis
76948	Echo guide, ova aspiration
93005	Electrocardiogram, tracing
71010	Chest x-ray
77326	Radiation therapy dose plan

HCPCS Code	Short Description
77327	Brachytx isodose calc interm
77331	Special radiation dosimetry
77333	Radiation treatment aid(s)
77370	Radiation physics consult
77399	External radiation dosimetry
77470	Special radiation treatment

However, we note several inherent features of multiple bill claims that prevented us from the further creation of ''pseudo'' singles. We discussed these obstacles in detail in the August 9, 2002 proposed rule (67 FR 52092, 52108 through 52111) and the November 1, 2001 final rule (66 FR 66718 and 66743 through 66746).

Notwithstanding the obstacles in creating additional ''pseudo'' single claims, we have received a number of suggestions from outside sources providing options to this approach. Some of the suggestions involved complex methodologies driven by lengthy tables of codes and complex logic that focused on creating ''pseudo'' singles by packaging specific packaged HCPCS codes with specific payable HCPCS codes. While we appreciate the time and attention spent by various parties interested in this issue, our review of the suggestions and our empirical analysis of the most specific and detailed recommendation using the data used to develop the APC relative weights for the APC Panel's February 2004 meeting indicated that code-specific packaging would add a significant amount of time and complexity to the ratesetting process and would require involved annual maintenance to accurately update the code sets used in the suggested methodology each year. Moreover, we would experience only a modest increase in ''pseudo'' single claims.

Further, code-specific packaging does not appear to appreciably increase the volume of single bills available for calculating medians for those APCs that are currently derived from a small volume of total claims. We believe that the observed modest improvements in the ''pseudo'' single claims volume from code-specific packaging can be attributed to the number and variety of services billed on multiple procedure claims, which often have complex HCPCS code combinations. These complex claims cannot be reduced to single bills by packaging the costs for a few procedures. In light of these findings, we are not proposing to adopt any code-specific packaging proposals. However, we would review and consider any other specific proposals that we received as comments.

Other suggestions included recommendations that the costs in packaged revenue codes and packaged HCPCS codes be allocated separately to paid HCPCS codes based on the prior year's payment weights or payment rates for the single procedures. Still other suggestions recommended that we allocate the packaged costs in proportion to the charges or to the costs for the major procedures based on the current year's claims. We are concerned that using a prior year's median costs, relative weights or payment rates as the basis to allocate current year's packaged costs to current year costs for payable HCPCS codes may not be appropriate. For example, if two procedures are performed and one uses an expensive device, this methodology would split the costs of the device between the service that uses the device and a service that does not use the device, thus resulting in incorrect allocation of the packaged costs. Therefore, we are not proposing to incorporate these suggestions in our ratesetting methodology but we intend to examine them more thoroughly.

We continue to seek strategies that would enable us to use more multiple procedure claims and continue to explore whether there are techniques that could result in medians that are more representative of the relative cost of the services being furnished. However, at this time, we are not proposing a methodology beyond use of dates of service and the expanded bypass list. We solicit specific proposals provided in comments on how multiple procedure claims can be better used in calculating the relative payment weights.

B. Proposed Calculation of Median Costs for CY 2005

In this section of the preamble, we discuss the use of claims to calculate the proposed OPPS payment rates for CY 2005. (See the hospital outpatient prospective payment page on the CMS website on which this proposed rule is posted for an accounting of claims used in the development of the proposed rates: *www.cms.hhs.gov/hopps*.) The accounting of claims used in the development of the proposed rule is included under supplemental materials for this proposed rule. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, we note that below we discuss the files of claims that comprise the data sets that are available for purchase under a CMS data user contract. See *www.cms.hhs.gov/providers/hopps* for information about purchasing the following two OPPS data files: ''OPPS limited data set'' and ''OPPS identifiable data set''.

We are proposing to use the following methodology to establish the weights to be used to set payment rates for CY 2005:

We are proposing to use outpatient claims for full CY 2003 to set the weights for CY 2005. To begin the calculation of the weights for this proposed rule for CY 2005, we pulled all claims for outpatient services furnished in CY 2003 from the national claims history file. This is not the population of claims paid under the OPPS, but all outpatient claims (for example, ambulatory surgical center (ASC) claims reported on bill type 83, critical access hospital (CAH) claims, and hospital claims for clinical laboratory services for persons who are neither inpatients nor outpatients of the hospital).

We then excluded claims with condition code 04, 20, 21, 77. These are claims that providers submitted to Medicare knowing that no payment will 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, and the U.S. Virgin Islands because hospitals in those geographic areas are not paid under the OPPS.

We divided the remaining claims into three groups shown below. Groups 2 and 3 comprise the 96.7 million claims that contain hospital bill types paid under the OPPS.

1. Claims that were not bill types 12X, 13X, 14X (hospital bill types) or 76X (CMHC bill types). Other bill types, such as ASCs, bill type 83, are not paid under the OPPS and, therefore, these claims were not used to set OPPS payment.

2. Bill types 12X, 13X, or 14X (hospital bill types). These claims are hospital outpatient claims.

3. 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.)

In previous years, we have begun the CCR calculation process using the most recent available cost reports for all hospitals irrespective of whether any or all of the hospitals included actually filed hospital outpatient claims for the data period. However, for this proposed rule, we first limited the population of cost reports to only those for hospitals that filed outpatient claims in CY 2003 before determining whether the CCRs for such hospitals were valid. This initial limitation changed the distribution of CCRs used during the trimming process discussed below.

We then calculated the cost-to-charge ratios (CCRs) at a departmental level and overall for each hospital for which we had claims data. We did this using hospital specific data from the Hospital Cost Report Information System (HCRIS). We used the most recent available cost report data, in most cases, cost reports for CY 2001 or CY 2002. We used the most recent available cost report, whether submitted or settled. 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 and we then adjusted the most recent available submitted but not settled cost report using that ratio. We are proposing to use these same CCRs ratios for the final rule.

We then flagged CAHs, which are not paid under the OPPS, and hospitals with invalid CCRs. These included claims from hospitals without a CCR, for hospitals paid an all-inclusive rate, for hospitals with obviously erroneous CCRs (greater than 90 or less than .0001), and for hospitals with 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 departmental level by removing the CCRs for each cost center as outliers if they exceeded ±3 standard deviations of the geometric mean. We are proposing to use these trimmed CCRs for the final rule. In prior years, we did not trim CCRs at the departmental level. However, for CY 2005, we are proposing to trim at the departmental CCR level to eliminate aberrant CCRs that, if found in high volume hospitals, could skew the medians. We used a four-tiered hierarchy of cost center CCRs to match a cost center to a revenue code with the top tier being the most common cost center and the last tier being the default CCR. If a hospital's departmental CCR was deleted by trimming, we set the departmental CCR for that cost center to ''missing,'' so that another departmental CCR in the revenue center hierarchy could apply. If no other departmental CCR could apply to the revenue code on the claim, we used the hospital's overall CCR for the revenue code in question.

We then converted the charges on the claim by applying the CCR that we believed was best suited to the revenue code indicated on the line with the charge. See Table 18 for the allowed revenue codes. Revenue codes not on this list are those not allowed under the OPPS because their services cannot be paid under the OPPS (for example, inpatient room and board charges) and, thus, charges with those revenue codes were not packaged for creation of the OPPS median costs. If a hospital did not have a CCR that was appropriate to the revenue code reported for a line item charge (for example, a visit reported under the clinic revenue code but the hospital did not have a clinic cost center), we applied the hospital-specific overall CCR, except as discussed in section V.H. of this proposed rule for calculation of costs for blood.

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

We identified claims with condition code 41 as partial hospitalization services of CMHCs and removed 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 also removed claims for observation services to another file. We removed to another file claims that contain nothing but flu and pneumococcal pneumonia (virus) (''PPV'') vaccine. Influenza and PPV vaccines are paid at reasonable cost and, therefore, these claims are not used to set OPPS rates. We note that the two above mentioned separate files containing partial hospitalization claims and the observation services claims are included in the files that are available for purchase as discussed above.

We next copied line item costs for drugs, blood, and devices (the lines stay on the claim but are copied off 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 the per unit median for drugs, radiopharmaceuticals, and blood and blood products. The line-item costs were also used to calculate the per administration cost of drugs, radiopharmaceuticals, and biologicals (other than blood and blood products) for purposes of determining whether the cost of the item would be packaged or be paid separately. Section 1833(t)(16)(B) of the Act, as added by section 621(a)(2) of Pub. L. 108–173, requires the Secretary to lower to $50 the threshold for separate payment of drugs and biologicals and the per administration cost derived using these line-item cost data would be used to make that decision for CY 2005. As discussed in our November 7, 2003 final rule with comment period (68 FR 63398), we had also applied a $50 threshold for the CY 2004 update to the OPPS.

We then divided the remaining claims into five groups.

1. *Single Major Claims:* Claims with a single separately payable procedure, all of which would be used in median setting.

2. *Multiple Major Claims:* Claims with more than one separately payable procedure or multiple units for one payable procedure. As discussed below, some of these can be used in median setting.

3. *Single Minor Claims:* Claims with a single HCPCS code that is not separately payable. These claims may have a single packaged procedure or a drug code.

4. *Multiple Minor Claims:* Claims with multiple HCPCS codes that are not separately payable without examining dates of service. (For example, pathology codes are packaged unless they appear on a single bill by themselves. The multiple minor file has claims with multiple occurrences of pathology codes, with packaged costs

that cannot be appropriately allocated across the multiple pathology codes. However, by matching dates of service for the code and the reported costs through the "pseudo'' single creation process discussed earlier, a claim with multiple pathology codes may become several "pseudo'' single claims with a unique pathology code and its associated costs on each day. These "pseudo'' singles for the pathology codes would then be considered a separately payable code and would be used like claims in the single major claim file.

5. *Non-OPPS Claims:* Claims that contain no services payable under the OPPS are excluded from the files used for the OPPS. Non-OPPS claims have codes paid under other fee schedules, for example, DME or clinical laboratory.

We note that the claims listed in numbers 1 through 4 above are included in the data files that can be purchased as described above.

We set aside the single minor claims and the non-OPPS claims (numbers 3 and 5 above) because we did not use either in calculating median cost.

We then examined the multiple major and multiple minor claims (numbers 2 and 4 above) to determine if we could convert any of them to single major claims using the process described previously. We first grouped items on the claims by date of service. If each major procedure on the claim had a different date of service and if the line items for packaged HCPCS and packaged revenue codes had dates of service, we broke the claim into multiple "pseudo'' single claims based on the date of service.

After those single claims were created, we used a list of "bypass codes'' to remove separately payable procedures that are thought to contain limited costs or no packaged costs from a multiple procedure bill. A discussion of the creation of the list of bypass codes used for the creation of "pseudo'' single claims is contained in section III.A.2. of this preamble and the list of codes is provided in Table 17.

We excluded those claims that we were not able to convert to singles even after applying both of the techniques for creation of "pseudo'' singles. We then packaged the costs of packaged HCPCS (codes with status indicator "N'' on Addendum B to this proposed rule) and packaged revenue codes (listed in Table 18) into the cost of the single major procedure remaining on the claim.

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, 52.2 millions claims were left. This subset of claims is roughly one-half of the 96.7 million claims for bill types paid under the OPPS. Of these 52.2 million claims, we were able to use some portion of 48.5 million (93 percent) whole claims to create the 75 million single and "pseudo'' single claims for use in our CY 2005 median payment ratesetting.

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Table 18.--Proposed Packaged Services by Revenue Code

Revenue Code	Description
250	PHARMACY
251	GENERIC
252	NONGENERIC
254	PHARMACY INCIDENT TO OTHER DIAGNOSTIC
255	PHARMACY INCIDENT TO RADIOLOGY
257	NONPRESCRIPTION DRUGS
258	IV SOLUTIONS
259	OTHER PHARMACY
260	IV THERAPY, GENERAL CLASS
262	IV THERAPY/PHARMACY SERVICES
263	SUPPLY/DELIVERY
264	IV THERAPY/SUPPLIES
269	OTHER IV THERAPY
270	M&S SUPPLIES
271	NONSTERILE SUPPLIES
272	STERILE SUPPLIES

Revenue Code	Description
274	PROSTHETIC/ORTHOTIC DEVICES
275	PACEMAKER DRUG
276	INTRAOCULAR LENS SOURCE DRUG
278	OTHER IMPLANTS
279	OTHER M&S SUPPLIES
280	ONCOLOGY
289	OTHER ONCOLOGY
290	DURABLE MEDICAL EQUIPMENT
370	ANESTHESIA
371	ANESTHESIA INCIDENT TO RADIOLOGY
372	ANESTHESIA INCIDENT TO OTHER DIAGNOSTIC
379	OTHER ANESTHESIA
390	BLOOD STORAGE AND PROCESSING
399	OTHER BLOOD STORAGE AND PROCESSING
560	MEDICAL SOCIAL SERVICES
569	OTHER MEDICAL SOCIAL SERVICES
621	SUPPLIES INCIDENT TO RADIOLOGY
622	SUPPLIES INCIDENT TO OTHER DIAGNOSTIC
624	INVESTIGATIONAL DEVICE (IDE)
630	DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS
631	SINGLE SOURCE
632	MULTIPLE
633	RESTRICTIVE PRESCRIPTION
637	SELF-ADMINISTERED DRUG (INSULIN ADMIN. IN EMERGENCY DIABETIC COMA)
681	TRAUMA RESPONSE, LEVEL I
682	TRAUMA RESPONSE, LEVEL II
683	TRAUMA RESPONSE, LEVEL III
684	TRAUMA RESPONSE, LEVEL IV
689	TRAUMA RESPONSE , OTHER
700	CAST ROOM
709	OTHER CAST ROOM
710	RECOVERY ROOM
719	OTHER RECOVERY ROOM
720	LABOR ROOM
721	LABOR
762	OBSERVATION ROOM
810	ORGAN ACQUISITION
819	OTHER ORGAN ACQUISITION
942	EDUCATION/TRAINING

We also excluded claims that either had zero costs after summing all costs on the claim or for which CMS lacked an appropriate provider wage index. For the remaining claims, we then wage adjusted 60 percent of the cost of the claim (which we determined to be the labor-related portion), as has been our policy since initial implementation of

the OPPS, to adjust for geographic variation in labor-related 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. We used the pre-reclassified wage index proposed for IPPS published in the hospital IPPS proposed rule on May 18, 2004 (69 FR 28196), and corrected in the IPPS correction notice published on June 25, 2004 (69 FR 35919). These wage indices are reprinted in Addenda L and M to this proposed rule. We are proposing to use the pre-reclassified wage index for standardization because we believe that it better reflects the true costs of items and services in the area in which the hospital is located than the post-reclassification wage index, and would result in the most accurate adjusted median costs.

We then excluded claims that were outside 3 standard deviations from the geometric mean cost for each HCPCS code. We used the remaining claims to calculate median costs for each separately payable HCPCS code; first, to determine the applicability of the ''2 times'' rule, and second, to determine APC medians as based on the claims containing the HCPCS codes assigned to each APC. As stated previously, 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 medians and reassigned HCPCS codes to different APCs as deemed appropriate. See section III.B. of this preamble for a discussion of the proposed HCPCS code assignment changes that resulted from examination of the medians and for other reasons. The APC medians were recalculated after we reassigned the affected HCPCS codes.

For discussion of the medians for blood and blood products see V.I of this preamble. For a discussion of the medians for APC 0315 (Level II Implantation of Neurostimulator), APC 0422 (Implantation of the BARD Endoscopic Suturing System), and APC 0651 (Complex Interstitial Radiation Application), see sections III.C.2.a., III.C.2.b., and III.C.2.c., respectively, of this preamble.

For discussion of the medians for APCs that require one or more devices when the service is performed, see section III.C. of this preamble. For a discussion of the median for observation services, see section VII.D. of this preamble and for a discussion of the median for partial hospitalization, see section X.C.

C. Proposed Adjustment of Median Costs for CY 2005

1. Device-Dependent APCs

Table 19 contains a list of APCs consisting of HCPCS codes that cannot be provided without one or more devices. For CY 2002, we used external data in part to establish the median used for weight setting. At that time, many devices were eligible for pass-through payment. For that year, we estimated that the total amount of pass-through payments would far exceed the limit imposed by statute. To reduce the amount of a pro rata adjustment to all pass-through items, we packaged 75 percent of the cost of the devices (using external data furnished by commenters on the August 24, 2001 proposed rule) into the median cost for the APCs associated with these pass-through devices. The remaining 25 percent of the cost was considered to be pass-through payment. (See section VI. of this preamble for discussion of pro rata adjustment.)

For CY 2003 OPPS, which was based on CY 2001 claims data, we found that the median costs for certain device-dependent APCs when all claims were used were substantially less than the median costs used for 2002. We were concerned that using the medians calculated from all claims would result in payments for some APCs that would not compensate the hospital even for the cost of the device. Therefore, we calculated a median cost using only claims from hospitals that had separately billed the pass-through device in CY 2001 (that is, hospitals whose claims contained the ''C'' code for the pass-through device). Furthermore, for any APC (whether device dependent or not) where the median cost would have decreased by 15 percent or more from CY 2002 to CY 2003, we limited decreases in median costs by 15 percent plus half of the amount of any reduction beyond 15 percent (see 68 FR 47984). For a few particular device-dependent APCs for which we believed that access to the service was in jeopardy, we blended external data furnished by commenters on the August 9, 2002 proposed rule (see 67 FR 57092) with claims data to establish the median cost used to set the payment rate. For CY 2003, we also eliminated the HCPCS ''C'' codes for the devices and returned to providers those claims on which the deleted device codes were used. (See 67 FR 66750, November 1, 2002, and section IV.B. of this preamble for a discussion regarding the required use of C codes for specific categories of devices.)

For CY 2004 OPPS, which was based on CY 2002 claims data, we used only claims on which hospitals had reported devices to establish the median cost for certain APCs. We did this because we found that the median costs calculated when we used all claims for these services were inadequate to cover the cost of the device if the device was not separately coded on the claim. Using only claims containing the code for the device (a ''C'' code) provided costs that were closer to those used for CY 2002 and CY 2003 for these services. For a few particular APCs in which we believed that access to the service was in jeopardy, we used external data provided by commenters on the August 12, 2003 proposed rule in a 50-percent blend with claims data to establish the device portion of the median cost used to set the payment rate (68 FR 63423). We also reinstated, but on a voluntary basis, the reporting of ''C'' codes for devices.

Thus, in developing the median costs for device-dependent APCs for CYs 2002, 2003, and 2004, we applied certain adjustments to our claims data as provided under the authority of section 1833(t)(9)(A) of the Act to ensure equitable payments to the hospitals for the provision of such services. We have continued to receive comments from interested parties as part of the APC Panel process urging us to determine whether the claims data that would be used in calculating the median costs for device-dependent APCs for payment in CY 2005 would represent valid relative costs for these services. Careful analysis of the CY 2003 data that we are proposing to use in calculating the median costs for the CY 2005 OPPS revealed problems similar to those discussed above in calculating device-dependent APC median costs based solely on claims data. Calculation of the CY 2005 median costs for the device-dependent APCs indicated that some of the medians appeared to appropriately reflect the costs of the services, including the cost of the device, and others did not. Of the 43 device-dependent APCs analyzed , 31 have median costs that are lower than the medians on which the OPPS payments were based in CY 2004. In contrast, 11 device-dependent APCs have median costs that are higher than the medians on which OPPS payments were based in CY 2004.

The differences between the CY 2004 payment medians and the proposed CY 2005 median costs using CY 2003 claims data are attributable to several factors. As discussed above, the CY 2004 payment medians were based on a subset of claims that contained the codes for the devices without which the procedures could not be performed, and several APCs were adjusted using external data. The proposed CY 2005 OPPS median costs were calculated based on all single bills, including ''pseudo'' single bills, for the services in the APCs and (not a subset of claims containing device codes) and were not adjusted using external data. In fact, as stated previously, we eliminated device coding requirements for hospitals in CY 2003. Consequently, there were no device codes reported for almost all devices in the CY 2003 claims data. Thus, it was not possible to use only the CY 2003 claims data containing device codes to calculate APC device-dependent medians as was done in CY 2004. Similarly, it was not possible to calculate a percentage of the APC cost attributed to device codes as would be needed to use external data to adjust CY 2003 claims data.

In light of these data issues for CY 2005, we examined several alternatives to using CY 2003 claims data to calculate the proposed median costs for device-dependent APCs. We considered using CY 2004 OPPS medians with an inflation factor, as recommended by the Panel and by several outside organizations. We rejected this option because it would not recognize any changes in relative costs for these APCs and would not direct us towards our goal of using all single claims data as the basis for payment weights for all OPPS services.

We also considered using the medians we calculated from all single bills with no adjustments. However, the results of using this approach without increasing the payments for some important high cost services for CY 2005 could result in the closing of hospital programs that provide these services thus, jeopardizing access to needed care. Therefore, we did not adopt this approach.

In addition, we considered subsetting claims based on the presence of charges in certain revenue codes. Specifically, we reviewed those codes where we require that hospitals report charges for the devices required for these procedures. These revenue codes include: 272, sterile supplies; 275, pacemakers; 278, other implants; 279, other supplies/devices; 280, oncology; 289, other oncology; and 624, investigational devices. We determined that the medians increased for some device-dependent APCs when we used only claims with a charge in at least one of these revenue codes, but our analysis provided no reliable evidence that the charges that would be found in these revenue codes were necessarily for the cost of the device.

Further, we considered using CY 2002 claims to calculate a ratio between the median calculated using all single bills and the median calculated using only claims with HCPCS codes for devices on them, and applying that ratio to the median calculated using all single bills from CY 2003 claims data. We rejected this option because it assumes that the relationship between the costs of the claims with and without codes for devices is a valid relationship not only for CY 2002 but CY 2003 as well. It also assumes no changes in billing behavior. We have no reason to believe either of these assumptions is true and, therefore, we did not choose this option.

In summary, we considered and rejected all of the above options. We have given special treatment to the device-dependent APCs for the past 3 years, recognizing that, in a new payment system, hospitals need time to establish correct coding processes and, considering the need to ensure continued access to these important services. After 3 years of such consideration, we believe that it is time to begin a transition to the use of pure claims data for these services (reflected in these APCs) to ensure the appropriate relativity of the median costs for all payable OPPS services. Our goal is to establish payment rates that provide appropriate relative payment for all services paid under the OPPS without creating payment disincentives that may reduce access to care.

We do not believe that any of the above options considered would help us realize our goal. We believe that the better payment approach for determining median costs for device-dependent APCs in CY 2005 would be to base such medians on the greater of (1) median costs calculated using CY 2003 claims data, or (2) 90 percent of the APC payment median for CY 2004 for such services. We believe that some variation in median costs is to be expected from year to year, and we believe that recognizing up to a 10-percent variation in our proposed payment approach would be a reasonable limit.

We believe that this proposed adjustment methodology provides an appropriate transition to eventual use of all single bill claims data without adjustment and that the methodology moves us towards the goal of using all single bill data without adjustment by CY 2007. It is a simple and easily understood methodology for adjusting median costs. Where reductions occur compared to CY 2004 OPPS, we believe that, under this methodology, the reductions will be sufficiently modest that providers will be able to accommodate them without ceasing to furnish services that Medicare beneficiaries need.

We considered applying the adjustment methodology we used for all APCs, including device-dependent APCs, for CY 2003 OPPS, but we saw no advantage to doing so. We applied that methodology to the identified device-dependent APCs only for 1 year, and we applied it where we had already made an adjustment by calculating the median costs based only on claims containing ''C'' codes for the devices. Therefore, for device-dependent APCs, there was a double adjustment intended to soften the effects of the first year of cessation of pass-through payment for devices (that is, we adjusted the higher ''C'' code medians, not all single bill medians). Devices have been off pass-through for several years now and for CY 2005 OPPS, we are unable to calculate medians based only on claims containing ''C'' codes. Therefore, we do not view the circumstances across the 2 years as comparable.

In addition, beginning in CY 2005, we are proposing to require hospitals to bill device-dependent procedures using the appropriate ''C'' codes for the devices. This requirement is limited to only those APCs to which the proposed use of CY 2004 medians would apply. We believe that this proposal would mitigate against the reduction of access to care while encouraging hospitals to bill correctly for the services they furnish. We intend this requirement to be the first step towards use of all available single bill claims data to establish medians for device-dependent APCs. Our goal is to use all single bills for device APCs by the CY 2007 OPPS, which we expect to base on data from claims for services in CY 2005. We further discuss our coding proposal in section III.C.3. of this preamble.

We welcome comments on all aspects of theses issues and particularly on steps that can be taken in the future to transition from the historic payment medians to claims based median costs for OPPS ratesetting for these important services.

Table 19 is sorted by percentage difference between changes in the CY 2004 and CY 2005 APC payment rate CY 2004 to CY 2005. It also contains the CY 2004 OPPS payment medians, the CY 2005 OPPS proposed medians (using

single bill claims from January 1, 2003, through December 31, 2003), and the medians derived from the proposed adjustment processes discussed further below.

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Table 19.--Proposed Median Costs for Device-Dependent APCs

APC	Description	SI	Final 2004 OPPS APC Median*	Proposed Unadjusted 2005 OPPS NPRM APC Median	Percentage change from 2004 to 2005	2005 OPPS total bill frequency	Proposed Adjusted 2005 OPPS Median
0119	Implantation of Infusion Pump	T	$7,765.02	$703.79	-90.94%	440	$6,988.52
0087	Cardiac Electrophysiologic Recording/Mapping	T	$2,294.94	$547.44	-76.15%	10,393	$2,065.45
0106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	T	$3,399.05	$1,627.90	-52.11%	3,770	$3,059.15
0107	Insertion of Cardioverter-Defibrillator	T	$19,431.68	$12,100.48	-37.73%	6,101	$17,488.51
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	T	$26,092.91	$17,313.63	-33.65%	4,310	$23,483.62
0032	Insertion of Central Venous/Arterial Catheter	T	$662.31	$456.51	-31.07%	68,110	$596.08
0222	Implantation of Neurological Device (APC0039 was part of APC 0222 in 2003)	T	$13,383.79	$9,477.10	-29.19%	4,865	$12,045.41
0384	GI Procedures with Stents (new for 2004; no prior APC)	T	$1,669.39	$1,223.75	-26.69%	18,096	$1,502.45
0082	Coronary Atherectomy	T	$6,352.89	$4,791.05	-24.58%	541	$5,717.60
0039	Implantation of Neurostimulator (new for 2004 OPPS; codes formerly in APC 0222)	S	$13,555.80	$10,335.53	-23.76%	1,592	$12,200.22
0048	Arthroplasty with Prosthesis (some codes now in APC 415 were in APC 48 in 2003 and 2004)	T	$2,966.13	$2,389.31	-19.45%	2,887	$2,669.52
0081	Non-Coronary Angioplasty or Atherectomy	T	$2,018.99	$1,730.80	-14.27%	112,613	$1,817.09
0083	Coronary Angioplasty and Percutaneous Valvuloplasty	T	$3,412.47	$2,967.94	-13.03%	7,177	$3,071.22
0090	Insertion/Replacement of Pacemaker Pulse Generator	T	$5,581.04	$4,943.36	-11.43%	7,463	$5,022.94
0122	Level II Tube changes and Repositioning	T	$510.80	$468.41	-8.30%	16,589	$468.41
0648	Breast Reconstruction with Prosthesis	T	$3,113.43	$2,872.85	-7.73%	1,103	$2,872.85
0227	Implantation of Drug Infusion Device	T	$9,270.36	$8,558.82	-7.68%	3,013	$8,558.82
0654	Insertion/Replacement of a permanent dual chamber pacemaker	T	$6,495.61	$6,045.29	-6.93%	19,265	$6,045.29
0674	Prostate Cryoablation (device was on pass through in 2003; 2004 median includes device with external data; 2005 median is "C" code median)**	T	$6,915.08	$6,477.78	-6.32%	1,265	$6,477.78
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	T	$6,754.63	$6,338.69	-6.16%	4,475	$6,338.69

APC	Description	SI	Final 2004 OPPS APC Median*	Proposed Unadjusted 2005 OPPS NPRM APC Median	Percentage change from 2004 to 2005	2005 OPPS total bill frequency	Proposed Adjusted 2005 OPPS Median
0386	Level II Prosthetic Urological Procedures (APCs 385 and 386 were combined in a single, different APC in 2003)	S	$6,699.79	$6,304.06	-5.91%	4,776	$6,304.06
0681	Knee Arthroplasty	T	$5,657.87	$5,348.34	-5.47%	730	$5,348.34
0653	Vascular Reconstruction/Fistula Repair with Device	T	$1,731.08	$1,636.73	-5.45%	26,194	$1,636.73
0040	Level II Implantation of Neurostimulator Electrodes (new for 2004; codes were in APC 225 for 2003)	S	$3,002.98	$2,857.90	-4.83%	9,513	$2,857.90
0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	T	$8,225.23	$7,882.97	-4.16%	13,579	$7,882.97
0167	Level III Urethral Procedures	T	$1,730.23	$1,662.49	-3.92%	9,440	$1,662.49
0229	Transcatherter Placement of Intravascular Shunts	T	$3,572.98	$3,444.24	-3.60%	36,558	$3,444.24
0086	Ablate Heart Dysrhythm Focus	T	$2,590.21	$2,553.76	-1.41%	7,757	$2,553.76
0385	Level I Prosthetic Urological Procedures (APCs 385 and 386 were combined in a single different APC in 2003)	S	$3,870.60	$3,830.79	-1.03%	1,191	$3,830.79
0085	Level II Electrophysiologic Evaluation	T	$2,041.13	$2,034.42	-0.33%	16,844	$2,034.42
0104	Transcatheter Placement of Intracoronary Stents	T	$4,765.05	$4,759.66	-0.11%	18,865	$4,759.66
0115	Cannula/Access Device Procedures	T	$1,478.06	$1,496.14	1.22%	95,354	$1,495.84
0656	Transcatheter Placement of Intracoronary Drug Eluting Stents (medians for 2003 and 2004 were created by adding $1200 to the median for APC 104)	T	$5,965.05	$6,067.71	1.72%	4,008	$6,067.71
0080	Diagnostic Cardiac Catheterization	T	$2,075.91	$2,119.83	2.12%	356,596	$2,119.83
0313	Brachytherapy	S	$795.83	$816.80	2.63%	13,354	$816.80
0680	Insertion of Patient Activated Event Recorders	S	$3,621.15	$3,721.58	2.77%	1,862	$3,721.58
0202	Level X Female Reproductive Proc	T	$2,246.87	$2,320.21	3.26%	12,464	$2,320.21
0652	Insertion of Intraperitoneal Catheters	T	$1,558.34	$1,620.25	3.97%	4,882	$1,620.25
0225	Level I Implementation of Neurostimulator Electrodes (contained codes in APC 040 in 2003 OPPS)	S	$11,873.72	$12,387.73	4.33%	1,315	$12,387.73
0259	Level VI ENT Procedures	T	$22,643.98	$24,086.02	6.37%	795	$24,086.02

APC	Description	SI	Final 2004 OPPS APC Median*	Proposed Unadjusted 2005 OPPS NPRM APC Median	Percentage change from 2004 to 2005	2005 OPPS total bill frequency	Proposed Adjusted 2005 OPPS Median
0670	Intravenous and Intracardiac Ultrasound	S	$1,582.08	$1,727.28	9.18%	5,646	$1,727.28
0425	Level II Arthroplasty with prosthesis (new for 2005; codes were in APC 48; data for 2003 and 2004 is from APC 0048)	T	$2,966.13	$5,792.39	95.28%	688	$5,792.39
0418	Left ventricular lead (code was in new tech APC 1547 at $850 for 2004)	T		$4,531.79		432	$4,531.79

As a result of our data analysis for device-dependent APCs, we are proposing to make the following changes in our methodology for setting the CY 2005 payment rates for device-dependent APC for the reasons specified:

We propose to remove APC 0226, Implantation of drug infusion reservoir, from the list of device-dependent APCs and to use its unadjusted single bill median of $2,793.30 as the basis for the payment weight. CPT code 62360, Implantation or replacement of device for intrathecal or epidural drug infusion, subcutaneous reservoir, is assigned to APC 0226. In 2002, when we packaged 75 percent of the cost of the device into the payment for the procedure with which the device was billed to reduce the pro rata adjustment, we inadvertently packaged the cost of an implantable infusion pump (C1336 and C1337) rather than that of a drug reservoir. Our data indicate that the reservoir used in performing CPT code 62360 cost considerably less than an implantable infusion pump, and we believe that the median cost for APC 0226 appropriately reflects the relative cost of the service and the required device.

In addition, we are proposing to delete APC 0048, Arthroplasty with Prosthesis, from the list of device-dependent APCs and adjust the median costs for this APC because we believe that the proposed CY 2005 median cost for this APC as restructured is reasonable and appropriate. Based on our careful analysis of the CY 2003 claims data for this APC, we believe the difference between the CY 2004 and CY 2005 median cost is attributable to the migration of certain high cost CPT codes (23470, 24361, 24363, 24366, 25441, 25442, 25446) from APC 0048 to new APC 0425, Level II Arthroplasty with Prosthesis and, as such, this change would not adversely limit beneficiary access to this important service. Therefore, we are not proposing to apply a device-dependent adjustment to the median cost for APC 0048.

Further, we are proposing to move HCPCS code 52282 (Cystoscopy, implant stent), from APC 0385, Level I Prosthetic Urological Procedure, and assign it to APC 0163, Level IV Cystourethoscopy and other Genitourinary Procedures, for clinical homogeneity. As titled, APC 0385 was intended for the assignment of certain urological procedures that require the use of prosthetics. However, HCPCS code 52282 requires the use of a stent rather than a urological prosthetic. Therefore, we are proposing to reassign HCPCS code 52282 to APC 0163. Recalculation of the median cost for APC 385 after reassigning HCPCS code 52282 yields a median cost for that APC that is consistent with its CY 2004 median payment. Thus, we are not proposing to apply a device-dependent adjustment to the median cost for APC 0385.

Lastly, we are proposing to remove HCPCS code 49419 (Insert abdom cath for chemo tx), from APC 0119, Implantation of Infusion Pump, and assign it to APC 0115, Cannula/Access Device Procedures, to achieve clinical homogeneity within APC 0115. Unlike all the other codes assigned to APC 0115, HCPCS code 49419 does not require the use of an infusion pump. Rather, this code is used when inserting an intraperitoneal cannula or catheter with a subcutaneous reservoir. Thus, we believe it would be more appropriate clinically to reassign HCPCS code 49419 to APC 0115 that includes procedures which require the use of devices similar to that required for code 49419.

2. Proposed Treatment of Specified APCs

a. APC 0315 Level II Implantation of Neurostimulator

The code, CPT code 61866, (Implant neurostim arrays) was brought to our attention by means of an application for a new device category for transitional pass-through payment for the Kinetra® neurostimulator, a dual channel neurostimulator currently approved and used for Parkinson's disease. We denied approval for a new device category for the Kinetra® neurostimulator because the device is described by a previously existing category, C1767, "Generator, neurostimulator (implantable)''.

The manufacturer of Kinetra® stated that the AMA created CPT 61886 to accommodate implantation of the Kinetra® neurostimulator and that no services other than implantation of the Kinetra® are currently described by that CPT code. Even though, the Kinetra® did not receive full FDA pre-market approval until December 2003, hospital outpatient claims were reported in CYs 2002 and 2003 (289 total claims in 2003) for this device. The manufacturer asserted that these claims must have been miscoded because the Kinetra® could not have been used in performing CPT code 61886 before obtaining FDA approval in December 2003. Therefore, the manufacturer did not believe that the device cost could be included in the median for CPT code 61886, which has been assigned to APC 222.

In examining the CY 2003 claims for CPT code 61866, we noted that many of the claims also contained codes for procedures related to treatment with cranial nerve stimulators, including the placement of electrodes for cranial nerve stimulation. The placement of the cranial neurostimulator electrodes used with the Kinetra® are currently an inpatient rather than outpatient procedure. Therefore, we would not expect patients being prepared for cranial nerve stimulation to also have a Kinetra® neurostimulator for deep brain stimulation for Parkinson's disease placed at the same time. Thus, it seems possible that the CY 2003 claims for CPT code 61886, generally, are incorrectly coded and do not include

the dual chamber neurostimulator in the reported charges.

Prior to the availability of the dual channel neurostimulator Kinetra® for bilateral deep brain stimulation, it is our understanding that patients diagnosed with Parkinson's disease had two single channel neurostimulator generators implanted in the same operative session. According to the Kinetra® manufacturer, this device will now replace the insertion of two single channel neurostimulators and the cost of the Kinetra® is equivalent to the cost of two single channel neurostimulators. Given this information, we examined our CY 2003 claims data and found that 69 single claims were reported for patients with a diagnosis of Parkinson's disease and that 2 single channel neurostimulator pulse generators (CPT code 61885) were implanted on the same day. The median cost for these claims was $20,631. Other than the device costs, we believe the procedural costs for the insertion of two single channel devices or with one dual channel device should be roughly comparable. Therefore, we are proposing to establish a new APC 0315, Level II Implantation of Neurostimulator, for CPT code 61886, and assign it a median cost of $20,631. Because of our concern that hospitals correctly code OPPS claims for CPT code 61886, we are also proposing to require device coding (''C'' code) for APC 0315 to improve the coding on all claims for placement of a dual channel cranial neurostimulator pulse generator or receiver, as we are proposing for APC 0039, Implantation of Neurostimulator, for placement of a single channel cranial neurostimulator, discussed in Section III. C3 of this preamble.

b. APC 0651, Complex Interstitial Radiation Application

For CY 2003 APC 0651, HCPCS code 77778 (Complex interstitial radiation source application) was not to be used for prostate brachytherapy because we created HCPCS codes G0256 (Prostate brachytherapy with palladium sources) and G0261 (Prostate brachytherapy with iodine sources) in which we packaged the cost of placement of needles or catheters and sources into a single APC payment for each G code (*see* 67 FR 66779). When we calculated the median from all single bills for HCPCS code 77778 from CY 2003 data for CY 2005 OPPS, we found that 73 percent of the single bills for this APC were for prostate brachytherapy and, therefore, were miscoded. The median for APC 0651, using all single bills, including those miscoded for prostate brachytherapy, was $2,641.67. When we removed the incorrectly coded claims for prostate brachytherapy, the median is $1,491.39, which is the amount we are proposing for payment for CY 2005 OPPS for APC 0651. This median is considerably higher than the median cost of $589.72 for CY 2004 OPPS (from CY 2002 claims data).

We believe that this adjusted median is appropriate for APC 0651 when used for prostate brachytherapy because the service described by HCPCS code 77778 is only one of several components of the payment for the service in its entirety. When it is used for prostate brachytherapy, hospitals should also bill for the placement of the needles and catheters using HCPCS code 55859 and should also bill the brachytherapy sources separately. Hospitals will be paid for both APCs and for the cost of sources. Under the amounts proposed, the total unadjusted payment would be $3,544.59, plus the hospital's cost for the brachytherapy sources.

Section 621(b)(1) of Pub. L. 108–173 specifically provides separate payment in CY 2005 ''* * * for a device of brachytherapy, consisting of a seed or seeds (or radioactive source)'' * * * at the hospital's charge adjusted to cost. We are proposing to package the cost of other services such as the needles or catheters into the payment for the brachytherapy APCs and not to pay on the same basis as the brachytherapy sources because the law does not include needles and catheters in its definition of brachytherapy sources to be paid on charges adjusted to cost.

We also recognize that APC 0651 is used for brachytherapy services other than prostate brachytherapy and that, in some of those cases, there are no other codes for placement of the needles or catheters. In those cases, which are represented in the claims we used to calculate the median (once the miscoded claims for prostate brachytherapy were excluded), we believe that the charges for HCPCS code 77778 may include the placement of the needles or catheters and therefore the median may be somewhat overstated when used as the basis of payment for prostate brachytherapy and the other forms of brachytherapy that have codes for placement of needles and catheters. Similarly, the median may be understated when used to pay for brachytherapy services for which there are no separate HCPCS codes for needle or catheter placement. We considered whether to create new G codes for the placement of catheters and needles for the brachytherapy services for which such codes do not exist, but we were concerned that doing so might create unneeded complexity and that the existing data may not support establishing medians for the new codes. We are requesting comments on how to address those services for which there are currently no HCPCS codes for placement of needles and catheters for brachytherapy applications.

c. APC 0659, Hyperbaric Oxygen Therapy

Over the past year, we have received a number of questions about billing and payment for HCPCS code C1300, Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval. In light of these issues, we have carefully examined the CY 2003 single procedure claims data that we are proposing to use to calculate the CY 2005 proposed median for APC services. Based on our examination of single procedure claims filed for HCPCS code C1300 in CY 2003, we believe that the claims for these services were either miscoded or the therapy was aborted before its completion. The claims that we examined reflected a pattern that is inconsistent with the clinical delivery of this service. Hyperbaric oxygen therapy (HBOT) is prescribed for clinical conditions such as promoting the healing of chronic wounds. It is typically prescribed on average for 90 minutes and therefore, you would expect hospitals to bill multiple units of HBOT to achieve full body hyperbaric oxygen therapy. In addition to the therapeutic time spent at full hyperbaric oxygen pressure, treatment involves additional time for achieving full pressure (descent), providing air breaks to prevent neurological and other complications from occurring during the course of treatment, and returning the patient to atmospheric pressure (ascent). Our examination of the claims data revealed that providers who billed multiple units of C1300 reported a consistent charge for each ''30 Minute'' unit. Conversely, providers who billed only a single unit of C1300, suggesting either a miscoded or aborted service, reported a charge that was 3 to 4 times greater than the per ''30 minute'' unit reported by providers billing multiple units of HCPCS code C1300. While, it appears that many of the single procedure HBOT claims that we examined, represented billing for a full 90 to 120 minutes of HBOT (including ascent, descent, and air break time), they were improperly billed as 1 unit rather than as 3 or 4 units of HBOT. Consequently, this type of incorrect coding would result in an inappropriately high per 30 minute median cost for HBOT or a median cost for HBOT of $177.96 derived using single service claims and ''pseudo''

single service claims. This is a significant issue because HBOT is the only procedure assigned to APC 0659.

Our analysis of the HBOT claims data further revealed that about 40 percent of all HBOT claims included packaged costs. To confirm our belief that these packaged costs were not associated with HBOT, we examined the other major payable procedures billed in conjunction with HBOT. As a result, we identified billed services such as drug administration and wound debridement that we would typically expect to have associated with packaged services. We also looked at the magnitude of packaged costs in our single bills and found the majority of these costs were small, less than $30, and concentrated in revenue codes 25X, Pharmacy, and 27X, Medical/Surgical Supplies.

As a result of these coding anomalies, we are proposing to calculate our proposed ''30 minute'' median cost for APC 0659, using a total of 30,736 claims containing multiple units or multiple occurrences of HBOT, about 97 percent of all HBOT claims. Based on our finding, we are proposing to exclude claims with only one unit of HBOT. Using this proposed methodology, the proposed median cost per unit of C1300 is $82.91. Based on hospitals' charges on correctly coded claims, we believe this estimate is much more accurate for 30 minutes of HBOT. Thus, we are proposing a median cost for APC 0659 of $82.91 for CY 2005.

d. APC 0422, Implantation of the BARD Endoscopic Suturing System

For CY 2005, we are proposing to establish APC 0422 for Level II Upper GI Procedures. Code C9703 (the Bard Endoscopic Suturing System) was placed in that APC based on clinical and resource homogeneity as compared with the other services in the APC. Currently, code C9703 is assigned to new technology APC 1555, with a payment of $1,650. Median cost for code C9703 was based on CY 2002 claims and was somewhat lower than the established payment level. However, our examination of CY 2003 claims data for APC 422 revealed that 137 of the 171 single claims for code C9703 were from a single institution with an extremely low and consistent cost per claim. We do not believe that these 137 claims represent the service described by code C9703, which includes an upper gastrointestinal endoscopy along with suturing of the esophagogastric junction. Therefore, in establishing the median for APC 0422, we did not use these 137 claims, which we believe were incorrectly coded.

3. Proposed Required Use of ''C'' Codes for Devices

An important ancillary issue in regard to using hospital outpatient claims data to calculate median costs for device-dependent APC is whether to require that hospitals bill the HCPCS codes for the devices that are required to be used to provide the services in these APCs. We deleted these HCPCS codes for devices in CY 2003 because hospitals objected to the complexity of this coding, and we believed that hospitals would charge for the devices in appropriate revenue codes. Our review of the claims data does not support this belief. Hospitals do not appear to routinely include the charges for the devices they use when they bill for the related services in the device-dependent APCs. Therefore, we are also considering requiring hospitals to code devices for APCs to improve the quality of the claims data in support of our transition to the use of all single claims to establish payment rates for these APCs. We make this proposal cautiously, as we realize that it imposes a burden on hospitals to code the devices.

Specifically, for CY 2005 OPPS, we are proposing to require coding of devices required for APCs for which we propose to adjust the median costs for CY 2005 OPPS. The APCs and the devices that are proposed for device coding are displayed in Table 20 below. Specifically, if one device is shown for one APC, that device would have to be billed on the claim for a service in that APC or the claim would be returned to the provider for correction. If more than one device is shown for one APC, the provider would be required to bill one of the device codes shown on the same claim with the service in that APC for the claim to be accepted.

We are also proposing to require coding of C1900 (Left Ventricular lead) required to perform the service described in APC 0418, Left Ventricular Lead, because the service cannot be done without the lead and, because the device has been billed separately for pass-through payment in CYs 2003 and 2004. We believe that continued coding of the device would not impose a burden on hospitals. Similarly, because of our concerns regarding the correct coding of claims for CPT code 61886 (Implant neurostim arrays), assigned to APC 0315 (discussed in greater detail in section III.C.2.a. of the preamble), we are proposing to require device coding for APC 0315, Level II Implantation of Neurostimulator, to improve the coding on claims for placement of a dual channel cranial neurostimulator pulse generator or receiver, just as we are proposing to require device coding for APC 0039, Implantation of Neurostimulator, for placement of a single channel cranial Neurostimulator as noted below.

Table 20 below displays the APCs for which we are proposing to require ''C'' codes and the ''C'' code edits we are proposing to require for each APC. We welcome comments on the proposed ''C'' code requirements.

BILLING CODE 4120–01–P

APC	Description	APC Status Indicator	Proposed Device Code	Device Long Descriptor
0032	Insertion of Central Venous/Arterial Catheter	T	C1751	CATHETER, INFUSION, INSERTED PERIPHERALLY, CENTRALLY OR MIDLINE (OTHER THAN HEMODIALYSIS)
0039	Implantation of Neurostimulator (new for 2004 OPPS; codes formerly in APC 222)	S	C1767	GENERATOR, NEUROSTIMULATOR (IMPLANTABLE)
0081	Non-Coronary Angioplasty or Atherectomy	T	C1885	CATHETER, TRANSLUMINAL ANGIOPLASTY, LASER
		T	C1714	CATHETER, TRANSLUMINAL ATHERECTOMY, DIRECTIONAL
		T	C1724	CATHETER, TRANSLUMINAL ATHERECTOMY, ROTATIONAL
		T	C1725	CATHETER, TRANSLUMINAL ANGIOPLASTY, NON-LASER (MAY INCLUDE GUIDANCE, INFUSION/PERFUSION CAPABILITY)
		T	C2628	CATHETER, OCCLUSION

APC	Description	APC Status Indicator	Proposed Device Code	Device Long Descriptor
0082	Coronary Atherectomy	T	C1714	CATHETER, TRANSLUMINAL ATHERECTOMY, DIRECTIONAL
		T	C1724	CATHETER, TRANSLUMINAL ATHERECTOMY, ROTATIONAL
0083	Coronary Angioplasty and Percutaneous Valvuloplasty	T	C1725	CATHETER, TRANSLUMINAL ANGIOPLASTY, NON-LASER (MAY INCLUDE GUIDANCE, INFUSION/PERFUSION CAPABILITY)
		T	C1726	CATHETER, BALLOON DILATATION, NON-VASCULAR
0087	Cardiac Electrophysiologic Recording/Mapping	T	C1730	CATHETER, ELECTROPHYSIOLOGY, DIAGNOSTIC, OTHER THAN 3D MAPPING (19 OR FEWER ELECTRODES)
		T	C1731	CATHETER, ELECTROPHYSIOLOGY, DIAGNOSTIC, OTHER THAN 3D MAPPING (20 OR MORE ELECTRODES)
		T	C1732	CATHETER, ELECTROPHYSIOLOGY, DIAGNOSTIC/ABLATION, 3D OR VECTOR MAPPING
		T	C1733	CATHETER, ELECTROPHYSIOLOGY, DIAGNOSTIC/ABLATION, OTHER THAN 3D OR VECTOR MAPPING, OTHER THAN COOL-TIP
		T	C1766	INTRODUCER/SHEATH, GUIDING, INTRACARDIAC ELECTROPHYSIOLOGICAL, STEERABLE, OTHER THAN PEEL-AWAY
		T	C1892	INTRODUCER/SHEATH, GUIDING, INTRACARDIAC ELECTROPHYSIOLOGICAL, FIXED-CURVE, PEEL-AWAY
		T	C1893	INTRODUCER/SHEATH, GUIDING, INTRACARDIAC ELECTROPHYSIOLOGICAL, FIXED-CURVE, OTHER THAN PEEL-AWAY
0090	Insertion/Replacement of Pacemaker Pulse Generator	T	C1786	PACEMAKER, SINGLE CHAMBER, RATE-RESPONSIVE (IMPLANTABLE)
		T	C2620	PACEMAKER, SINGLE CHAMBER, NON RATE-RESPONSIVE (IMPLANTABE)
0106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	T	C1777	LEAD, CARDIOVERTER-DEFIBRILLATOR, ENDOCARDIAL SINGLE COIL (IMPLANTABLE)
		T	C1779	LEAD, PACEMAKER, TRANSVENOUS VDD SINGLE PASS
		T	C1895	LEAD, CARDIOVERTER-DEFIBRILLATOR, ENDOCARDIAL DUAL COIL (IMPLANTABLE)
		T	C1896	LEAD, CARDIOVERTER-DEFIBRILLATOR, OTHER THAN ENDOCARDIAL SINGLE OR DUAL COIL (IMPLANTABLE)
		T	C1899	LEAD, PACEMAKER/CARDIOVERTER-DEFIBRILLATOR COMBINATION (IMPLANTABLE)
0107	Insertion of Cardioverter-Defibrillator	T	C1721	CARDIOVERTER-DEFIBRILLATOR, DUAL CHAMBER (IMPLANTABLE)
		T	C1722	CARDIOVERTER-DEFIBRILLATOR, SINGLE CHAMBER (IMPLANTABLE)
		T	C1882	CARDIOVERTER-DEFIBRILLATOR, OTHER THAN SINGLE OR DUAL CHAMBER (IMPLANTABLE)

APC	Description	APC Status Indicator	Proposed Device Code	Device Long Descriptor
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	T	C1721	CARDIOVERTER-DEFIBRILLATOR, DUAL CHAMBER (IMPLANTABLE)
		T	C1722	CARDIOVERTER-DEFIBRILLATOR, SINGLE CHAMBER (IMPLANTABLE)
		T	C1882	CARDIOVERTER-DEFIBRILLATOR, OTHER THAN SINGLE OR DUAL CHAMBER (IMPLANTABLE)
0119	Implantation of Infusion Pump	T	C1772	INFUSION PUMP, PROGRAMMABLE (IMPLANTABLE)
		T	C1891	INFUSION PUMP, NON-PROGRAMMABLE, PERMANENT (IMPLANTABLE)
0222	Implantation of Neurological Device (APC 0039 was part of APC 0222 in 2003)	T	C1767	GENERATOR, NEUROSTIMULATOR (IMPLANTABLE)
0315	Implantation of neurostimularo array	T	C1767	GENERATOR, NEUROSTIMULATOR (IMPLANTABLE)
0384	GI Procedures with Stents (new for 2004; no prior APC)	T	C1874	STENT, COATED/COVERED, WITH DELIVERY SYSTEM
		T	C1875	STENT, COATED/COVERED, WITHOUT DELIVERY SYSTEM
		T	C1876	STENT, NON-COATED/NON-COVERED, WITH DELIVERY SYSTEM
		T	C1877	STENT, NON-COATED/NON-COVERED, WITHOUT DELIVERY SYSTEM
		T	C2617	STENT, NON-CORONARY, TEMPORARY, WITHOUT DELIVERY SYSTEM
		T	C2625	STENT, NON-CORONARY, TEMPORARY, WITH DELIVERY SYSTEM
0418	Left ventricular lead (code was in new tech APC 1547 at $850 for 2004)	T	C1900	LEAD, LEFT VENTRICULAR CORONARY VENOUS SYSTEM
0674	Prostate Cryoablation (device was on pass through in 2003; 2003 median does not include device; 2004 median includes device with external data)**	T	C2618	PROBE, CRYOABLATION

In addition, we are considering expanding the device coding requirements in the future. We believe that, by requiring device coding for a small subset of device-dependent APCs each year, we would minimize the marginal annual coding burden on hospitals and begin to improve data for these APCs, which have consistently proven to be problematic. We believe coding of devices is essential if we are to improve the accuracy of claims data sufficiently to better calculate the correct relative costs of device-dependent APCs in relation to the other services paid under the OPPS.

We request that the public inform us of the device codes that are essential to the procedures contained in the device-dependent APCs contained in Table 20. The alphanumeric HCPCS codes for devices that were reactivated for CY 2004 OPPS can be found on the CMS website at *www.cms.hhs.gov/providers* under coding. They are in the section of alphanumeric codes that begin with the initial letter ''C.'' Comments regarding the device codes that should be required with the APCs listed in Table 20 should contain the APC and identify all device codes that may be essential to the performance of the procedures identified in the APC. Ideally, the comments will include a narrative that explains how the device is inserted.

4. Submission of External Data

We would consider external data submitted with respect to any APC to the extent that such data enable us to verify or adjust claims data where we are convinced that such an adjustment to the median cost is appropriate. All comments and any data we use would be available for public inspection and commenters should not expect that any data furnished as part of the comment would be withheld from public inspection. Parties who submit external data for devices should also submit a strategy that can be used to determine what part of the median cost represents the device to which the external data applies. External data that are likely to be of optimal use should meet the following criteria:

- Represent a diverse group of hospitals both by location (for example, rural and urban) and by type (for example, community and teaching). We would prefer that commenters identify each hospital, including location with city and State, nonprofit vs. for profit status, teaching vs. nonteaching status, and the percent of Medicare vs. non-Medicare patients receiving the service. A pseudo identifier could be used for the hospital identification. Data should be submitted both ''per hospital'' and in the aggregate.
- Identify the number of devices billed to Medicare by each hospital as well as any rebates or reductions for bulk purchase or similar discounts and identify the characteristics of providers to which any such price rebates or reductions apply.
- Identify all HCPCS codes with which each item would be used.
- Identify the source of the data.
- Include both the charges and costs for each hospital for CY 2003.

Meeting the criteria would enable us to compare our CY 2003 claims data to the submitted external data and help us determine whether the submitted data

are representative of hospitals that submit claims under the OPPS.

We note that information containing beneficiary-specific information (for example, medical records, and invoices with beneficiary identification on it) must be altered, if necessary, to remove any individually identifiable information, such as information that identifies an individual, diagnoses, addresses, telephone numbers, attending physician, medical record number, and Medicare or other insurance number. Moreover, individually identifiable beneficiary medical records, including progress notes, medical orders, test results, and consultation reports must not be submitted to us. Similarly, photocopies of checks from hospitals or other documents that contain bank routing numbers must not be submitted to us.

D. Proposed Calculation of Scaled OPPS Payment Weights

Using the median APC costs discussed previously, we calculated the proposed relative payment weights for each APC for CY 2005. As in prior years, we scaled all the relative payment weights to APC 0601, Mid-Level Clinic Visit, because it is one of 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. Using CY 2003 data, the proposed median cost for APC 0601 is $57.32 for CY 2005.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes and wage index changes be made in a manner that assures that aggregate payments under the OPPS for CY 2005 are neither greater than nor less than the aggregate payments that would have been made without the changes. To comply with this requirement concerning the APC changes, we compared aggregate payments using the CY 2004 relative weights to aggregate payments using the CY 2005 proposed weights. Based on this comparison, we are proposing to make an adjustment of the weights for purposes of budget neutrality. The weights that we are proposing for CY 2005, which incorporate the recalibration adjustments explained in this section, are listed in Addendum A and Addendum B to this proposed rule.

Section 1833(t)(14)(H) of the Act, as added by section 621(a)(1) of Pub. L. 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) provides the payment rates for certain specified covered outpatient drugs. Therefore, the incremental cost of those specified covered outpatient drugs (as discussed in section II.J. of this proposed rule) is excluded from the budget neutrality calculations but the base median cost of the drugs continues to be a factor in the calculation of budget neutrality. Accordingly, we calculated median costs for the specified covered outpatient drugs to which this section applies and used those medians and the frequencies in the calculation of the scaler for budget neutrality.

Under section 1833(t)(16)(C) of the Act, as added by section 621(b)(1) of Pub. L. 108–173, payment for devices of brachytherapy consisting of a seed or seeds (or radioactive source) is to be made at charges adjusted to cost for services furnished on or after January 1, 2004 and before January 1, 2006. As we stated in our January 6, 2004 interim final rule, charges for the brachytherapy sources will not be used in determining outlier payments and payments for these items will be excluded from budget neutrality calculations, consistent with our practice under the OPPS for items paid at cost. (*See* section VII.G. of this proposed rule.)

IV. Proposed Payment Changes for Devices

[If you choose to comment on this section, please indicate the caption ''Devices'' at the beginning of your comment.]

A. Pass-Through Payments for Devices

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

Section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3, years. This period begins with the first date on which a transitional pass-through payment is made for any medical device that is described by the category. In our November 7, 2003 final rule with comment period (68 FR 63437), we specified six device categories currently in effect that would cease to be eligible for pass-through payment effective January 1, 2005.

The device category codes became effective April 1, 2001, under the provisions of the BIPA. Prior to pass-through device categories, we paid for pass-through devices under the OPPS on a brand-specific basis. All of the initial category codes that were established as of April 1, 2001, have expired; 95 categories expired after CY 2002 and 2 categories expired after CY 2003. All of the categories listed in Table 21, along with their expected expiration dates, were created since we published the criteria and process for creating additional device categories for pass-through payment on November 2, 2001 (66 FR 55850 through 55857). We based the expiration dates for the category codes listed in Table 21 on the date on which a category was first eligible for pass-through payment.

There are six categories for devices that would have been eligible for pass-through payments for at least 2 years as of December 31, 2004. In our November 7, 2003 final rule with comment period, we finalized the December 31, 2004 expiration dates for these six categories. (Three other categories listed in Table 21, C1814, C1818, and C1819, would expire on December 31, 2005.) The six categories that would expire as of December 31, 2004, are C1783, C1884, C1888, C1900, C2614, and C2632, as indicated in Table 23. Each category includes devices for which pass-through payment was first made under the OPPS in CY 2002 or CY 2003.

In the November 1, 2002 final rule, we established a policy for payment of devices included in pass-through categories that are due to expire (67 FR 66763). For CY 2003, we packaged the costs of the devices no longer eligible for pass-through payments into the costs of the procedures with which the devices were billed in CY 2001. There were few exceptions to this established policy (brachytherapy sources for other than prostate brachytherapy, which is now also separately paid in accordance with section 621(b)(2) of Pub. L. 108–173). For CY 2004, we continued to apply this policy for categories that expired on January 1, 2004.

2. Proposal for CY 2005

We are proposing to continue to base the expiration date for a device category on the earliest effective date of pass-through payment status of the devices that populate the category. This basis for determining the expiration date of a device category is the same as that used in CY 2003 and CY 2004.

We are also proposing that payment for the devices that populate the six categories that would cease to be eligible for pass-through payment after December 31, 2004, would be made as part of the payment for the APCs with which they are billed. This methodology for packaging device cost is consistent with the packaging methodology that we

describe in section III. of this proposed rule. To accomplish this, we are proposing to package the costs of devices that would no longer be eligible for pass-through payment in CY 2005 into the HCPCS codes with which the devices are billed.

We note that category C1819 (Tissue localization excision device) was added subsequent to our proposed rule for CY 2004. We first announced the start date and the proposed expiration date for this device category in our November 7, 2003 final rule with comment period. Therefore, we are proposing to maintain the category's December 31, 2005 expiration date. We invite comments on the proposed expiration date for category C1819.

Table 21.--List Of Current Pass-Through Device Categories By Expiration Date

HCPCS Codes	Category Long Descriptor	Date(s) Populated	Expiration Date
C1888	Catheter, ablation, non-cardiac, endovascular (implantable)	7/1/02	12/31/04
C1900	Lead, left ventricular coronary venous system	7/1/02	12/31/04
C1783	Ocular implant, aqueous drainage assist device	7/1/02	12/31/04
C1884	Embolization protective system	1/1/03	12/31/04
C2614	Probe, percutaneous lumbar discectomy	1/1/03	12/31/04
C2632	Brachytherapy solution, iodine-125, per mCi	1/1/03	12/31/04
C1814	Retinal tamponade device, silicone oil	4/1/03	12/31/05
C1818	Integrated keratoprosthesis	7/1/03	12/31/05
C1819	Tissue localization excision device	1/1/04	12/31/05

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

1. Background

In the November 30, 2001 final rule, we explained the methodology we used to estimate the portion of each APC rate that could reasonably be attributed to the cost of the associated devices that are eligible for pass-through payments (66 FR 59904). Beginning with the implementation of the CY 2002 OPPS update (April 1, 2002), we deducted from the pass-through payments for the identified devices an amount that reflected the portion of the APC payment amount that we determined was associated with the cost of the device, as required by section 1833(t)(6)(D)(ii) of the Act. In the November 1, 2002 final rule, we published the applicable offset amounts for CY 2003 (67 FR 66801).

For the CY 2002 and CY 2003 OPPS updates, to estimate the portion of each APC rate that could reasonably be attributed to the cost of an associated pass-through device eligible for pass-through payment, we used claims data from the period used for recalibration of the APC rates. Using those claims, we calculated a median cost for every APC without packaging the costs of associated ''C'' codes for device categories that were billed with the APC. We then calculated a median cost for every APC with the costs of the associated device category ''C'' codes that were billed with the APC packaged into the median. Comparing the median APC cost without device packaging to the median APC cost including device packaging enabled us to determine the percentage of the median APC cost that is attributable to the associated pass-through devices. By applying those percentages to the APC payment rates, we determined the applicable amount to be deducted from the pass-through payment, the ''offset'' amount. We created an offset list comprised of any APC for which the device cost was at least 1 percent of the APC's cost.

As first discussed in our November 1, 2002 final rule (67 FR 66801) the offset list that we publish each year is a list of offset amounts associated with those APCs with identified offset amounts developed using the methodology described above. As a rule, we do not know in advance which procedures and APCs may be billed with new categories. An offset amount is therefore applied only when a new device category is billed with an APC appearing on the offset list. The list of potential offsets for CY 2004 is currently published on our website *www.cms.hhs.gov,* as ''Device Related Portions of Ambulatory Payment Classification Costs for 2004.''

For CY 2004, we modified our policy for applying offsets to device pass-through payments. Specifically, we indicated that we would apply an offset to a new device category only when we could determine that an APC contains costs associated with the device. We continued our existing methodology for determining the offset amount, described above. We were able to use this methodology to establish the device offset amounts for CY 2004 because providers reported device codes (C codes) on the CY 2002 claims used for CY 2004 OPPS. However, for the CY 2005 update to the OPPS, we are proposing to use CY 2003 claims that do not include device coding. (Section III. of this proposed rule contains a fuller discussion of our proposed requirement for use of ''C'' codes for CY 2005.)

In the CY 2004 OPPS update, we reviewed the device categories eligible for continuing pass-through payment in CY 2004 to determine whether the costs associated with the device categories are packaged into the existing APCs. Based on our review of the data for the categories existing in CY 2004, we determined that there were no close or identifiable costs associated with the devices relating to the respective APCs that are normally billed with them. Therefore, for those device categories, we set the offset to $0 for CY 2004.

2. Proposal for CY 2005

For CY 2005, we are proposing to continue to review each new device category on a case-by-case basis as we did in CY 2004 to determine whether device costs associated with the new category are packaged into the existing APC structure. We are also proposing to set the offsets to $0 for the currently

established categories that would continue for pass-through payment into CY 2005. If, during CY 2005, we create a new device category and determine that our data contain identifiable costs associated with the devices in any APC, we would adjust the APC payment if the offset is greater than $0. If we determine that device offsets greater than $0 are appropriate for any new category that we create during CY 2005, we are proposing to announce the offset amounts in the program transmittal that announces the new category.

Further, for CY 2005, we are proposing to use the device percentages (portion of the APC median cost attributable to the packaged device) that we developed for potential offsets in CY 2004 and to apply these percentages to the CY 2005 payment amounts to obtain CY 2005 offset amounts, in cases where we determine that an offset is appropriate. We propose to use the device percentage developed for CY 2004 because, as noted above, for the CY 2005 update to the OPPS, we are using CY 2003 claims that do not include device codes. Therefore, we are not easily able to determine the device portions of APCs for CY 2003 claims data. We have posted the list of device-dependent APCs and their respective device portions on the CMS website: *www.cms.hhs.gov*.

V. Proposed Payment Changes for Drugs, Biologicals, Radiopharmaceutical Agents, and Blood and Blood Products

A. Transitional Pass-Through Payment for Additional Costs of Drugs and Biologicals

[If you choose to comment on issues in this section, include the caption "Pass-Through'' at the beginning of your comment.]

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 BBRA, this provision required 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 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 BIPA (Pub. L. 106–554), on December 21, 2000).

Transitional pass-through payments are also required for certain "new'' drugs, devices and biological agents that were not being paid for as a hospital OPD service as of December 31, 1996, and whose cost is "not insignificant'' in relation to the OPPS payment for the procedures or services associated with the new drug, device, or biological. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years. Pass-through drugs and biological agents are identified by status indicator "G.''

The process to apply for transitional pass-through payment for eligible drugs and biological agents can be found on pages of our CMS website: *www.cms.hhs.gov*. If we revise the application instructions in any way, we will post the revisions on our website and submit the changes to the Office of Management and Budget (OMB) for approval, as required under the Paperwork Reduction Act (PRA). Notification of new drugs and biological application processes is generally posted on the OPPS website at: *www.cms.hhs.gov/hopps.*

2. Expiration in CY 2004 of Pass-Through Status for Drugs and Biologicals

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 any longer than 3 years. The drugs whose pass-through status will expire on December 31, 2004, meet that criterion. Table 22 lists the drugs and biologicals for which we are proposing that pass-through status would expire on December 31, 2004.

Table 22.--Proposed List of Drugs and Biologicals for Which Pass-Through Status Expires CY 2004

HCPCS	APC	Long Descriptor	Trade Name
J0583	9111	Injection, Bivalirudin, per 1 mg	Angiomax Inj (single source)
C9112	9112	Injection, Perflutren lipid microsphere, per 2 ml	Definity (single source)
C9113	9113	Injection, Pantoprazole sodium, per vial	Protonix (single source)
J1335	9116	Injection, Ertapenem sodium, per 500 mg	Invanz (single source)
J2505	9119	Injection, Pegfilgrastim, per 6 mg single dose vial	Neulasta (single source)
J9395	9120	Injection, Fulvestrant, per 25 mg	Faslodex (single source)
C9121	9121	Injection, Argotroban, per 5 mg	Acova (single source)
C9200	9200	Orcel, per 36 square centimeters	Orcel (single source)
C9201	9201	Dermagraft, per 37.5 square centimeters	Dermagraft (single source)
J2324	9114	Injection, Nesiritide, per 0.5 mg	Natrecor (single source)
J3315	9122	Injection, Triptorelin pamoate, per 3.75 mg	Trelstar depot Trelstar LA (single source)
J3487	9115	Injection, Zoledronic acid, per 1 mg	Zometa (single source)
Q0137	0734	Injection, Darbepoetin Alfa, 1 mcg (non-ESRD use)	Aranesp (single source)

3. Drugs and Biologicals With Proposed Pass-Through Status in CY 2005

We are proposing to continue pass-through status for CY 2005 for the drugs and biologicals listed in Table 23. The APCs and HCPCS codes for drugs and biologicals that we are proposing to continue with pass-through status in CY 2005 are assigned status indicator "G'' in Addendum A and Addendum B, respectively, to this proposed rule.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs (assuming that no pro rata reduction in pass-through payment is necessary) as the amount determined under section 1842(o) of the Act. Section 303(c) of Pub. L. 108–173 amends Title XVIII of the Act by adding new section 1847A. This new section establishes the use of the average sales price (ASP) methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. Therefore, in CY 2005, we are proposing to pay under the OPPS for drugs and biologicals with pass-through status consistent with the provisions of section 1842(o) of the Act as amended by Pub. L. 108–173 at a rate that is equivalent to the payment these drugs and biologicals would receive in the physician office setting, and established in accordance with the methodology described in the CY 2005 Physician Fee Schedule proposed rule (69 FR 47488).

We are further proposing to amend § 419.64 of the regulations to conform with these changes. Specifically, we propose to replace paragraphs (d)(1) and (d)(2) with paragraph (d) to provide that, subject to any reduction determined under § 419.62(b), the pass-through payment for a drug or biological equals the amount determined under section 1842(o) of the Act, minus the portion of the APC that we determine is associated with the drug or biological.

Section 1833(t)(6)(D)(i) of the Act also sets the amount of additional payment for pass-through eligible drugs and biologicals (the pass-through payment amount). The pass-through payment amount is the difference between the amount authorized under section 1842(o) of the Act, and the portion of the otherwise applicable fee schedule amount (that is, the APC payment rate) that the Secretary determines is associated with the drug or biological. As we explain in section V.B. of this proposed rule, we are proposing to make separate payment, beginning in CY 2005, for new drugs and biologicals with a HCPCS code consistent with the provisions of section 1842(o) of the Act as amended by Pub. L. 108–173 at a rate that is equivalent to the payment they would receive in a physician office setting, whether or not we have received a pass-through application for the item. Accordingly, beginning in CY 2005, the pass-through payment amount for new drugs and biologicals that we determine have pass-through status equals zero. That is, when we subtract the amount to be paid for pass-through drugs and biologicals under section 1842(o) of the Act, as amended by Pub. L. 108–173, from the portion of the otherwise

applicable fee schedule amount, or the APC payment rate associated with the drug or biological which would be the amount paid for drugs and biologicals under section 1842(o) of the Act as amended by Pub. L. 108–173, the resulting difference is equal to zero. Table 23 lists the drugs and biologicals for which we propose pass-through status continuing in CY 2005. Addendum B to this proposed rule lists the proposed CY 2005 rates for these pass-through drugs and biologicals based on data reported to CMS as of April 30, 2004.

Table 23.--Proposed List of Drugs and Biologicals for Which Pass-Through Status Continues In CY 2005

HCPCS	APC	Long Descriptor	Trade Name
C9123	9123	TransCyte, per 247 sq. cm	TransCyte
C9205	9205	Injection, Oxaliplatin, per 5 mg	Eloxatin
C9203	9203	Injection, Perflexane lipid microspheres, per single use vial	Imagent
J3486	9204	Injection, Ziprasidone mesylate, per 10 mg	Geodon
C9211	9211	Injection, IV, Alefacept, per 7.5 mg	Amevive
C9212	9212	Injection, IM, Alefacept, per 7.5 mg	Amevive
C9207	9207	Injection, IV, Bortezomib, per 3.5 mg	Velcade
C9208	9208	Injection, IV, Agalsidase beta, per 1 mg	Fabrazyme
C9209	9209	Injection, IV Laronidase, per 2.9 mg	Aldurazyme
C9217	9300	Injection, Sub Q, Omalizumab, per 150 mg vial	Xolair
C9210	9210	Injection, IV, Palonosetron HCI per 0.25 mg (250 microgram)	Aloxi
C9124	9124	Injection, daptomycin, per 1 mg	Cubicin
C9125	9125	Injection, risperidone, per 12.5 mg	Risperdal Consta
J2783	0738	Injection, rasburicase, 0.5 mg	Elitek
C9213	9213	Injection, Pemetrexed, per 10 mg	Alimta
C9214	9214	Injection, Bevacizumab, per 10 mg	Avastin
C9215	9215	Injection, Cetuximab, per 10 mg	Erbitux
C9216	9216	Abarelix for Injectable Suspension per 10 mg	Plenaxis
C9217	9300	Injection, Omalizumab, per 5 mg	Xolair

B. Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

[If you choose to comment on issues in this section, include "Drugs, Biologicals, and Radiopharmaceuticals NonPass-Throughs'' at the beginning of your comment.]

1. Background

Under the OPPS, we currently pay for drugs, biologicals including blood and blood products, and radiopharmaceuticals that do not have pass-through status in one of two ways: packaged payment and separate payment (individual APCs). We explained in the April 7, 2000 final rule (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 for within the national OPPS payment rate for the associated procedure or service. (Program Memorandum 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. Notwithstanding our commitment to package as many costs as possible, we are aware that packaging payments for certain drugs, biologicals, and radiopharmaceuticals, especially those that are particularly expensive or rarely used, might result in insufficient payments to hospitals, which could adversely affect beneficiary access to medically necessary services. As discussed in the November 7, 2003 OPPS final rule with comment period (68 FR 63445), we packaged payment for drugs, biologicals, and radiopharmaceuticals into the APCs with which they were billed if the median cost per day for the drug, biological, or radiopharmaceutical was less than $50. We established a separate APC payment for drugs, biologicals, and radiopharmaceuticals for which the median cost per day exceeded $50. Our rationale for establishing a $50 threshold was also discussed.

2. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

Section 621(a)(2) of Pub. L. 108–173 amended section 1833(t)(16) of the Act by adding a new subparagraph (B) to require that the threshold for establishing separate APCs for drugs and biologicals be set at $50 per administration for CYs 2005 and 2006. For CY 2005, we are proposing to continue our policy of paying separately for drugs, biologicals, and radiopharmaceuticals whose median cost per day exceeds $50 and packaging the cost of drugs, biologicals, and radiopharmaceuticals whose median cost per day is less than $50 into the procedures with which they are billed.

We calculated the median cost per day using claims data from January 1, 2003, to December 31, 2003, for all drugs, biologicals, and radiopharmaceuticals that had a HCPCS code during this time period and were paid (via packaged or separate payment) under the OPPS. Items such as single indication orphans drugs, certain vaccines, and blood and blood products were excluded from these calculations and our treatment of these is discussed separately in sections V.F., E., and I., respectively, of this preamble. In order to calculate the median cost per day for drugs, biologicals, and radiopharmaceuticals to determine their packaging status in CY 2005, we are proposing to use the methodology that was described in detail in the CY 2004 OPPS proposed rule (68 FR 47996 through 47997) and finalized in the CY 2004 final rule with comment period (68 FR 63444 through 63447). We are requesting comments on the methodology we are proposing to continue to use to determine the median cost per day of these items.

We are proposing to apply an exception to our packaging rule to one particular class of drugs, the injectible and oral forms of anti-emetic treatments. The HCPCS codes to which our exception would apply are listed below in Table 24. Our calculation of median cost per day for these products showed that, if we were to apply our packaging rule to these items, two of the injectible products would be packaged and one would be separately payable. In addition, two of the oral products would be separately payable and one would be packaged. Chemotherapy is very difficult for many patients to tolerate as the side effects are often debilitating. In order for beneficiaries to achieve the maximum therapeutic benefit from chemotherapy and other therapies with side effects of nausea and vomiting, anti-emetic use is often an integral part of the treatment regimen. We want to ensure that our 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 his or her physician. Therefore, we are proposing to pay separately for all six injectible and oral forms of anti-emetic products CY 2005.

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Table 24.--OPPS Anti-Emetic Products To Which We Propose To Apply Packaging Exception In CY 2005

HCPCS	Short Description	Median Cost per Day	CY 2005 Proposed Status Indicator without Exception
J1260	I. INJECTION, DOLASETRON MESYLATE, 10 MG	$42.94	N
Q0180	DOLASETRON MESYLATE, 100 MG, ORAL	$55.68	K
J1626	INJECTION, GRANISETRON HYDROCHLORIDE, 100 MCG	$55.06	K
Q0166	GRANISETRON HYDROCHLORIDE, 1 MG, ORAL	$43.91	N
J2405	INJECTION, ONDANSETRON HYDROCHLORIDE, PER 1 MG	$35.34	N
Q0179	ONDANSETRON HYDROCHLORIDE 8 MG, ORAL	$50.22	K

3. Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status That Are Not Packaged

a. Payment for Specified Covered Outpatient Drugs

Section 621(a)(1) of Pub. L. 108–173 amended section 1833(t) of the Act by adding a new subparagraph (14) that requires special classification of certain separately paid radiopharmaceutical agents and drugs or biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i), 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 exists 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.'' 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)(i) of the Act, as added by section 621(a)(1) of Pub. L. 108–173, specifies payment limits for three categories of specified covered outpatient drugs in CY 2004. Section 1833(t)(14)(F) of the Act defines the three categories of specified covered outpatient drugs based on section 1861(t)(1) and sections 1927(k)(7)(A)(ii), (k)(7)(A)(iii), and (k)(7)(A)(iv) of the Act. The categories of drugs are ''sole source drugs,'' ''innovator multiple source drugs,'' and ''noninnovator multiple source drugs.'' The definitions of these specified categories for drugs, biologicals, and radiopharmaceutical agents under Pub. L. 108–173 were discussed in the January 6, 2004 OPPS interim final rule with comment period (69 FR 822), along with our use of the Medicaid average manufacturer price database to determine the appropriate classification of these products. Because of the many comments received on the January 6, 2004 interim final rule with comment period, the classification of many of the drugs, biologicals, and radiopharmaceuticals changed from that initially published. These changes were announced to the public on February 27, 2004, Transmittal 112, Change Request 3144. Additional classification changes were implemented in Transmittals 3154 and 3322. We will finalize the interim final rule and address public comments associated with that rule when we finalize this proposed rule.

Section 1833(t)(14)(A) of the Act, as added by section 621(a)(1) of Pub. L. 108–173, also provides that payment for these specified covered outpatient drugs is to be based on its ''reference average wholesale price,'' that is, the AWP for the drug, biological, or radiopharmaceutical as determined under section 1842(o) of the Act as of May 1, 2003 (section 1833(t)(14)(G) of the Act). Section 621(a) of Pub. L. 108–173 also amended the Act by adding section 1833(t)(14)(A)(ii), which requires that:

- A sole source drug must, in CY 2005, be paid no less than 83 percent and no more than 95 percent of the reference AWP.
- An innovator multiple source drug must, in CY 2005, be paid no more than 68 percent of the reference AWP.
- A noninnovator multiple source drug must, in CY 2005, be paid no more than 46 percent of the reference AWP.

Section 1833(t)(14)(G) of the Act defines ''reference AWP'' as the AWP determined under section 1842(o) as of May 1, 2003. We interpret this to mean the AWP set under the CMS single drug pricer (SDP) based on prices published in the Red Book on May 1, 2003.

For CY 2005, we are proposing to determine the payment rates for specified covered outpatient drugs under the provisions of Pub. L. 108–173 by comparing the payment amount

calculated under the median cost methodology as done for procedural APCs (described previously in the preamble) to the AWP percentages specified in section 1833(t)(14)(A)(ii) of the Act.

Specifically, for sole source drugs, biologicals, and radiopharmaceuticals, we compared the payments established under the median cost methodology to their reference AWP. We are proposing to determine payment for sole source items as follows: If the payment falls below 83 percent of the reference AWP, we would increase the payment to 83 percent of the reference AWP. If the payment exceeds 95 percent of the reference AWP, we would reduce the payment to 95 percent of the reference AWP. If the payment is no lower than 83 percent and no higher than 95 percent of the reference AWP, we would make no change.

There is one sole source item, Co 57 cobaltous chloride (HCPCS code C9013), for which we cannot find a reference AWP amount. However, we have CY 2003 hospital claims data for C9013, and we are proposing to derive its payment rate using its median cost per unit. Therefore, we are proposing a CY 2005 payment rate for C9013 of $143.96. We request comments on our proposed methodology for determining the payment rate for C9013.

We note that there are three radiopharmaceutical products for which we are proposing a different payment policy in CY 2005. These products are represented by HCPCS codes A9526 (Ammonia N–13, per dose), C1775 (FDG, per dose (4–40 mCi/ml), and Q3000 (Rubidium-Rb-82). Radiopharmaceuticals are classified as a "specified covered outpatient drug'' according to section 1833(t)(14)(B)(i)(I) of the Act; and their payment is dependent on their classification as a single source, innovator multiple cource, or noninnovator multiple source product as defined by sections 1927(k)(7)(A)(iv), (ii), and (iii) of the Act. Upon further analysis of these items, we determined that these three products do not meet the statutory definition of a sole source item or a multiple source item. Pub. L. 108–173 requires us to pay for "specified covered outpatient drugs'' using specific payment methodologies based on their classification and does not address how payment should be made for items that do not meet the definition of a sole source or multiple source item. Therefore, we are proposing to set the CY 2005 payment rates for these three products based on median costs derived from CY 2003 hospital outpatient claims data, which would reflect hospital costs associated with these products. With regard to HCPCS code A9526, we have no hospital outpatient cost data for this HCPCS code. We received correspondence from an outside source stating that Rubidium-Rb-82 (HCPCS code Q3000) is an alternative product used for procedures for which Ammonia N–13 is also used and these two products are similar in cost. Therefore, we are proposing to establish a payment rate for Ammonia N–13 that is equivalent to the payment rate for Rubdium Rb–82.

We request comments on the proposed CY 2005 payment rates for these three items and invite commenters to submit external data if they believe the proposed CY 2005 payment rates for these items do not adequately represent actual hospital costs. Table 25 below lists the CY 2005 OPPS payment rates that we are proposing for these three radiophmaceutical products.

Table 25.—Proposed CY 2005 APC Payment Rates for Three Radiopharmaceuticals That Do Not Meet the Definition of a Single Source or Multiple Source Item

HCPCS Code	Status Indicator	APC	Short Description	CY 2005 Proposed Payment Rate
A9526	K	0737	Ammonia N-13, per dose	$111.91
C1775	K	1775	FDG, per dose (4-40 mCi/ml)	$220.50
Q3000	K	9025	Rubidium-Rb-82	$111.91

Table 25A lists the proposed payment amounts for sole source drugs, biologicals, and radiopharmaceuticals effective January 1, 2005 to December 31, 2005.

Table 25A.--Proposed OPPS Payment Amounts for Sole Source Drugs, Biologicals, and Radiopharmaceuticals for CY 2005

HCPCS	Status Indicator	APC	Short Description	CY 2005 Proposed Payment Rate
A4642	K	0704	Satumomab pendetide per dose	$1,390.25
A9500	K	1600	Technetium TC 99m sestamibi	$106.32
A9502	K	0705	Technetium TC99M tetrofosmin	$104.58
A9504	K	1602	Technetium tc 99m apcitide	$415.00
A9507	K	1604	Indium/111 capromab pendetid	$1,915.23
A9508	K	1045	Iobenguane sulfate I-131, per 0.5 mCi	$996.00
A9511	K	1095	Technetium TC 99m depreotide	$38.00
A9521	K	1096	Technetiumtc-99m exametazine	$778.13
A9605	K	0702	Samarium sm153 lexidronamm	$916.90
C1079	K	1079	CO 57/58 per 0.5 uCi	$221.78
C1080	K	1080	I-131 tositumomab, dx	$2,241.00
C1081	K	1081	I-131 tositumomab, tx	$19,422.00
C1082	K	9118	In-111 ibritumomab tiuxetan	$2,419.78
C1083	K	9117	Yttrium 90 ibritumomab tiuxetan	$20,948.25
C1091	K	1091	IN111 oxyquinoline,per0.5mCi	$373.50
C1092	K	1092	IN 111 pentetate per 0.5 mCi	$224.10
C1122	K	1122	Tc 99M ARCITUMOMAB PER VIAL	$1,079.00
C1178	K	1178	BUSULFAN IV, 6 Mg	$27.87
C1201	K	1201	TC 99M SUCCIMER, PER Vial	$118.52
C1305	K	1305	Apligraf	$1,130.88
C9003	K	9003	Palivizumab, per 50 mg	$576.51
C9008	K	9008	Baclofen Refill Kit-500mcg	$10.21
C9009	K	9009	Baclofen Refill Kit-2000mcg	$37.64
C9013	K	9013	Co 57 cobaltous chloride	$143.96
C9105	K	9105	Hep B imm glob, per 1 ml	$118.32
C9109	K	9109	Tirofiban hcl, 6.25 mg	$205.92
C9112	K	9112	Perflutren lipid micro, 2ml	$129.69
C9200	K	9200	Orcel, per 36 cm2	$991.85
C9201	K	9201	Dermagraft, per 37.5 sq cm	$529.54
C9202	K	9202	Octafluoropropane	$129.48
J0130	K	1605	Abciximab injection	$448.22
J0207	K	7000	Amifostine	$395.75
J0287	K	9024	Amphotericin b lipid complex	$19.09
J0288	K	0735	Ampho b cholesteryl sulfate	$15.20
J0289	K	0736	Amphotericin b liposome inj	$31.27
J0350	K	1606	Injection anistreplase 30 u	$2,353.53
J0583	K	9111	Bivalirudin	$1.52
J0585	K	0902	Botulinum toxin a per unit	$4.32

HCPCS	Status Indicator	APC	Short Description	CY 2005 Proposed Payment Rate
J0587	K	9018	Botulinum toxin type B	$7.68
J0637	K	9019	Caspofungin acetate	$32.65
J0850	K	0903	Cytomegalovirus imm IV /vial	$622.13
J1260	K	0750	Dolasetron mesylate	$14.38
J1327	K	1607	Eptifibatide injection	$11.21
J1438	K	1608	Etanercept injection	$135.56
J1440	K	0728	Filgrastim 300 mcg injection	$162.41
J1441	K	7049	Filgrastim 480 mcg injection	$274.40
J1563	K	0905	IV immune globulin	$68.48
J1564	K	9021	Immune globulin 10 mg	$0.75
J1565	K	0906	RSV-ivig	$16.55
J1626	K	0764	Granisetron HCl injection	$16.20
J1745	K	7043	Infliximab injection	$57.40
J1830	K	0910	Interferon beta-1b / .25 MG	$58.73
J1950	K	0800	Leuprolide acetate /3.75 MG	$451.98
J2020	K	9001	Linezolid injection	$32.15
J2324	K	9114	Nesiritide	$132.47
J2353	K	1207	Octreotide injection, depot	$71.66
J2354	K	7031	Octreotide inj, non-depot	$3.72
J2405	K	0768	Ondansetron hcl injection	$5.54
J2505	K	9119	Injection, pegfilgrastim 6mg	$2,448.50
J2788	K	9023	Rho d immune globulin 50 mcg	$30.38
J2792	K	1609	Rho(D) immune globulin h, sd	$17.95
J2820	K	0731	Sargramostim injection	$25.39
J2941	K	7034	Somatropin injection	$280.87
J2993	K	9005	Reteplase injection	$1,192.09
J3100	K	9002	Tenecteplase injection	$2,350.98
J3245	K	7041	Tirofiban hydrochloride	$411.85
J3305	K	7045	Inj trimetrexate glucoronate	$142.50
J3395	K	1203	Verteporfin injection	$1,274.05
J3487	K	9115	Zoledronic acid	$197.87
J7190	K	0925	Factor viii	$0.76
J7191	K	0926	Factor VIII (porcine)	$1.78
J7192	K	0927	Factor viii recombinant	$1.10
J7193	K	0931	Factor IX non-recombinant	$0.98
J7194	K	0928	Factor ix complex	$0.32
J7195	K	0932	Factor IX recombinant	$0.98
J7198	K	0929	Anti-inhibitor	$1.25
J7320	K	1611	Hylan G-F 20 injection	$203.70
J7504	K	0890	Lymphocyte immune globulin	$243.50
J7507	K	0891	Tacrolimus oral per 1 MG	$3.05
J7511	K	9104	Antithymocyte globuln rabbit	$312.41
J7517	K	9015	Mycophenolate mofetil oral	$2.46
J7520	K	9020	Sirolimus, oral	$6.23
J8510	K	7015	Oral busulfan	$2.08
J8520	K	7042	Capecitabine, oral, 150 mg	$2.96

HCPCS	Status Indicator	APC	Short Description	CY 2005 Proposed Payment Rate
J8700	K	1086	Temozolomide	$6.42
J9001	K	7046	Doxorubicin hcl liposome inj	$343.78
J9010	K	9110	Alemtuzumab injection	$510.70
J9020	K	0814	Asparaginase injection	$54.71
J9031	K	0809	Bcg live intravesical vac	$139.90
J9045	K	0811	Carboplatin injection	$129.96
J9151	K	0821	Daunorubicin citrate liposom	$64.60
J9170	K	0823	Docetaxel	$312.69
J9178	K	1167	Inj, epirubicin hcl, 2 mg	$24.14
J9185	K	0842	Fludarabine phosphate inj	$311.09
J9201	K	0828	Gemcitabine HCl	$105.73
J9202	K	0810	Goserelin acetate implant	$390.09
J9206	K	0830	Irinotecan injection	$127.33
J9213	K	0834	Interferon alfa-2a inj	$30.48
J9214	K	0836	Interferon alfa-2b inj	$13.00
J9215	K	0865	Interferon alfa-n3 inj	$8.17
J9217	K	9217	Leuprolide acetate suspnsion	$543.72
J9219	K	7051	Leuprolide acetate implant	$4,717.72
J9245	K	0840	Inj melphalan hydrochl 50 MG	$367.03
J9268	K	0844	Pentostatin injection	$1,683.24
J9270	K	0860	Plicamycin (mithramycin) inj	$93.80
J9293	K	0864	Mitoxantrone hydrochl / 5 MG	$313.96
J9310	K	0849	Rituximab cancer treatment	$437.83
J9350	K	0852	Topotecan	$697.76
J9355	K	1613	Trastuzumab	$50.79
J9390	K	0855	Vinorelbine tartrate/10 mg	$95.23
J9600	K	0856	Porfimer sodium	$2,274.78
Q0136	K	0733	Non esrd epoetin alpha inj	$11.09
Q0137	K	0734	Darbepoetin alfa, non esrd	$4.14
Q0166	K	0765	Granisetron HCl 1 mg oral	$39.04
Q0179	K	0769	Ondansetron HCl 8mg oral	$26.12
Q0180	K	0763	Dolasetron mesylate oral	$63.28
Q0187	K	1409	Factor viia recombinant	$1,410.34
Q2002	K	7022	Elliotts b solution per ml	$1.50
Q2003	K	7019	Aprotinin, 10,000 kiu	$12.51
Q2005	K	7024	Corticorelin ovine triflutat	$353.70
Q2006	K	7025	Digoxin immune fab (ovine)	$332.00
Q2007	K	7026	Ethanolamine oleate 100 mg	$63.29
Q2008	K	7027	Fomepizole, 15 mg	$10.04
Q2009	K	7028	Fosphenytoin, 50 mg	$5.31
Q2011	K	7030	Hemin, per 1 mg	$6.47
Q2013	K	7040	Pentastarch 10% solution	$131.99
Q2017	K	7035	Teniposide, 50 mg	$224.94
Q2018	K	7037	Urofollitropin, 75 iu	$56.59
Q2021	K	9057	Lepirudin	$130.30

HCPCS	Status Indicator	APC	Short Description	CY 2005 Proposed Payment Rate
Q2022	K	1618	VonWillebrandFactrCmplxperIU	$0.83
Q3002	K	1619	Gallium ga 67	$27.10
Q3003	K	1620	Technetium tc99m bicisate	$370.60
Q3005	K	1622	Technetium tc99m mertiatide	$31.13
Q3007	K	1624	Sodium phosphate p32	$94.98
Q3008	K	1625	Indium 111-in pentetreotide	$1,079.00
Q3011	K	1628	Chromic phosphate p32	$146.64
Q3012	K	1089	Cyanocobalamin cobalt co57	$85.49
Q3025	K	9022	IM inj interferon beta 1-a	$74.44

In order to determine the payment amounts for innovator multiple source and noninnovator multiple source forms of the drug, biological, or radiopharmaceutical, we compared the payments established under the median cost methodology to their reference AWP. For innovator multiple source items, we are proposing to set payment rates at the lower of the payment rate calculated under our standard median cost methodology or 68 percent of the reference AWP. For noninnovator or multiple source items, we are proposing to set payment rates at the lower of the payment rate calculated under our standard median cost methodology or 46 percent of the reference AWP. We followed this same methodology to set payment amounts for innovator multiple source and noninnovator multiple source specified covered to payment drugs that were implemented by the January 6, 2004 interim final rule with comment period.

Table 26 lists the proposed payment amounts for innovator and noninnovator multiple source drugs, biologicals, and radiopharmaceuticals effective January 1, 2005 to December 31, 2005.

Table 26.--Proposed OPPS Payment Amounts for Innovator and Noninnovator Multiple Source Drugs, Biologicals, and Radiopharmaceuticals for CY 2005

HCPCS	Status Indicator	APC	Short Description	2005 Proposed Payment Rate
A9505	K	1603	Thallous chloride TL 201/mci	$18.29
A9517	K	1064	Th I131 so iodide cap millic	$6.60
A9528	K	1064	Dx I131 so iodide cap millic	$6.60
A9529	K	1065	Dx I131 so iodide sol millic	$9.84
A9530	K	1065	Th I131 so iodide sol millic	$9.84
A9600	K	0701	Strontium-89 chloride	$410.45
C9400	K	9400	Thallous chloride, brand	$20.86
C9401	K	9401	Strontium-89 chloride,brand	$410.45
C9402	K	9402	Th I131 so iodide cap, brand	$6.60
C9403	K	9403	Dx I131 so iodide cap, brand	$6.60
C9404	K	9404	Dx I131 so iodide sol, brand	$9.84
C9405	K	9405	Th I131 so iodide sol, brand	$9.84
C9410	K	9410	Dexrazoxane HCl inj, brand	$125.24
C9411	K	9411	Pamidronate disodium, brand	$162.66
C9413	K	9413	Sodium hyaluronate inj, brand	$54.33
C9414	K	9414	Etoposide oral, brand	$27.72
C9415	K	9415	Doxorubic hcl chemo, brand	$6.94
C9417	K	9417	Bleomycin sulfate inj, brand	$130.56
C9418	K	9418	Cisplatin inj, brand	$11.42
C9419	K	9419	Inj cladribine, brand	$36.72
C9420	K	9420	Cyclophosphamide inj, brand	$4.10
C9421	K	9421	Cyclophosphamide lyo, brand	$3.50
C9422	K	9422	Cytarabine hcl inj, brand	$2.28
C9423	K	9423	Dacarbazine inj, brand	$8.24
C9424	K	9424	Daunorubicin, brand	$53.14
C9425	K	9425	Etoposide inj, brand	$1.22
C9426	K	9426	Floxuridine inj, brand	$97.92
C9427	K	9427	Ifosfomide inj, brand	$101.46
C9428	K	9428	Mesna injection, brand	$25.07
C9429	K	9429	Idarubicin hcl inj, brand	$13.45
C9430	K	9430	Leuprolide acetate inj, bran	$21.41
C9431	K	9431	Paclitaxel inj, brand	$95.84
C9432	K	9432	Mitomycin inj, brand	$45.70
C9433	K	9433	Thiotepa inj, brand	$66.98
C9435	K	9435	Gonadorelin hydroch, brand	$16.08
C9436	K	9436	Azathioprine parenteral,brnd	$44.61
C9438	K	9438	Cyclosporine oral, brand	$1.81
J1190	K	0726	Dexrazoxane HCl injection	$113.28
J1620	K	7005	Gonadorelin hydroch/ 100 mcg	$16.09
J2430	K	0730	Pamidronate disodium /30 MG	$128.74
J7317	K	7316	Sodium hyaluronate injection	$54.33
J7501	K	0887	Azathioprine parenteral	$30.18

HCPCS	Status Indicator	APC	Short Description	2005 Proposed Payment Rate
J7502	K	0888	Cyclosporine oral 100 mg	$1.81
J8560	K	0802	Etoposide oral 50 MG	$21.91
J9000	K	0847	Doxorubic hcl 10 MG vl chemo	$4.69
J9040	K	0857	Bleomycin sulfate injection	$88.32
J9060	K	0813	Cisplatin 10 MG injection	$7.73
J9065	K	0858	Inj cladribine per 1 MG	$24.84
J9070	K	0815	Cyclophosphamide 100 MG inj	$2.77
J9093	K	0816	Cyclophosphamide lyophilized	$2.36
J9100	K	0817	Cytarabine hcl 100 MG inj	$1.55
J9130	K	0819	Dacarbazine 100 mg inj	$6.14
J9150	K	0820	Daunorubicin	$35.94
J9181	K	0824	Etoposide 10 MG inj	$0.83
J9200	K	0827	Floxuridine injection	$66.24
J9208	K	0831	Ifosfomide injection	$72.81
J9209	K	0732	Mesna injection	$17.66
J9211	K	0832	Idarubicin hcl injection	$13.46
J9218	K	0861	Leuprolide acetate injeciton	$14.48
J9265	K	0863	Paclitaxel injection	$79.04
J9280	K	0862	Mitomycin 5 MG inj	$30.91
J9340	K	0851	Thiotepa injection	$45.31

b. Proposal To Treat Three Sunsetting Pass-Through Drugs as Specified Covered Outpatient Drugs

As discussed in section V.A.2 of the preamble, there are 13 drugs and biologicals whose pass-through status will expire on December 31, 2004. Table 22 lists these drugs and biologicals.

Pass-through payment was made for 10 of these 13 items as of December 31, 2002. Therefore, these 10 items now qualify as specified covered outpatient drugs under section 1833(t)(14) of the Act, as added by section 621(a) of Pub. L. 108–173, as described above. However, pass-through status for three of the pass-through drugs and biologicals that will expire on December 31, 2004 (C9121, Injection, argatroban; J9395, Fulvestrant; and J3315, Triptorelin pamoate), was first made effective on January 1, 2003. These items are specifically excluded from the definition of ''specified covered outpatient drugs'' in section 1833(t)(14)(B)(ii) of the Act, because they are not drugs or biologicals for which pass-through payment was first made on or before December 31, 2002. Pub. L. 108–173 does not address how to set payment for items whose pass-through status expires in CY 2005, but for which pass-through payment was not made as of December 31, 2002.

Therefore, we are proposing to pay for the three expiring pass-through items for which payment was first made on January 1, 2003 rather than on or before December 31, 2002 using the methodology described under section 1833(t)(14) of the Act for specified covered outpatient drugs. We believe that this methodology would allow us to determine appropriate payment amounts for these products in a manner that is consistent with how we pay for drugs and biologicals whose pass-through status was effective as of December 31, 2002, and that does not penalize those products for receiving pass-through status on or after January 1, 2003. Table 27 below lists the CY 2005 OPPS payment rates that we are proposing for these three drugs and biologicals.

Of the 13 products for which we are proposing that pass-through status expire on December 31, 2004, we are proposing to package two of them (C9113, Inj. Pantoprazole sodium and J1335, Ertapenum sodium) because their median cost per day falls below the $50 packaging threshold. The remaining 11 drugs and biologicals were determined to be sole source items and would be paid separately according to the payment methodology for sole source products described above.

We wish to note that darbepoetin alfa (Q0137) will be considered a specified covered outpatient drug in CY 2005. Payment for these drugs is governed under section 1833(t)(14) of the Act. Specifically, darbepoetin alfa will be paid as a sole-source drug at a rate between 83 and 95 percent of its reference AWP. Given the status required under 1833(t)(14) of the Act, as added by section 621(a)(1) of Pub. L. 108–173, we specifically solicit comment on whether we should again apply an equitable adjustment, made pursuant to 1833(t)(2)(E) of the Act, to the price of this drug.

Table 27—Proposed CY 2005 APC Payment Rates for Three Expiring Pass-Through Drugs and Biologicals That Will Be Treated As Specified Covered Outpatient Drugs

HCPCS	Status Indicator	Short Description	APC	2005 Proposed Payment Rate
J9395	K	Injection, Fulvestrant	9120	$79.65
J3315	K	Triptorelin pamoate	9122	$362.78
C9121	K	Injection, argatroban	9121	$12.45

c. Proposed CY 2005 Payment for New Drugs and Biologicals With HCPCS Codes and Without Pass-Through Application and Reference AWP

Pub. L. 108–173 does not address OPPS payment in CY 2005 for new drugs and biologicals 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 dictates payment for such drugs and biologicals in CY 2005, and because we have no hospital claims data to use in establishing a payment rate for them, we investigated other possible options to pay for these items in CY 2005. Clearly, one option is to continue packaging payment for these new drugs and biologicals that have their own HCPCS codes until we accumulate sufficient claims data to calculate median costs for these items. Another option is to pay for them separately using a data source other than our claims data. The first option is consistent with the approach we have taken in prior years when claims data for new services and items are not available to calculate median costs. However, because these new drugs and biologicals may be expensive, we are concerned that packaging these new drugs and biologicals may jeopardize beneficiary access to them. In addition, we do not want to delay separate payment for a new drug or biological solely because a pass-through application was not submitted.

Therefore, in CY 2005, we are proposing to pay for these new drugs and biologicals which do not have pass-through status at a rate that is equivalent to the payment they would receive in the physician office setting, which will be established in accordance with the methodology described in the CY 2005 Physician Fee Schedule proposed rule (69 FR 47488, 47520 through 47524). We note that this payment methodology is the same as the methodology that would be used to calculate the OPPS payment amount that pass-through drugs and biologicals would be paid in CY 2005 in accordance with section 1842(o) of the Act, as amended by section 303(b) of Pub. L. 108–173, and section 1847A of the Act. Thus, we would be treating new drugs and biologicals with established HCPCS codes the same, irrespective of whether pass-through status has been determined. We are also proposing to assign status indicator ''K'' to HCPCS codes for new drugs and biologicals for which we have not received a pass-through application.

In light of this proposal, we understand that manufacturers might be hesitant to apply for pass-through status. However, we do not believe there would be many instances in CY 2005 when we would not receive a pass-through application for a new drug or biological that has a HCPCS code. To avoid delays in setting an appropriate payment amount for new drugs and biologicals and to expedite the processing of claims, we strongly encourage manufacturers to continue submitting pass-through applications for new drugs and biologicals when FDA approval for a new drug or biological is imminent to give us advance notice to begin working to create a HCPCS code and APC. The preliminary application would have to be augmented by FDA approval documents and final package inserts once such materials become available. However, initiating the pass-through application process as early as possible would enable us to expedite coding and pricing for the new drugs and biologicals and accelerate the process for including them in the next available OPPS quarterly release.

We discuss in section V.D. of this preamble how we are proposing to pay in CY 2005 for new drugs and biologicals between their FDA approval date and assignment of a HCPCS code and APC. We share the desire of providers and manufacturers to incorporate payment for new drugs and biological into the OPPS as expeditiously as possible to eliminate potential barriers to beneficiary access and to minimize the number of claims that must be processed manually under the OPPS interim process for claims without established HCPCS codes and APCs, and we solicit public comments on our proposal.

d. Proposed Payment for Separately Payable NonPass-Through Drugs and Biologicals

As discussed in section V.B.2. of this preamble, for CY 2005, we used CY 2003 claims data to calculate the proposed median cost per day for drugs, biologicals, and radiopharmaceuticals that have an assigned HCPCS code and are paid either as a packaged or separately payable item under the OPPS. Section 1833(t)(14) of the Act, as added by section 621(a) of Pub. L. 108–173, specified payment methodologies for most of these drugs, biologicals, and radiopharmaceuticals. However, this provision did not specify how payment was to be made for separately payable drugs and biologicals that never received pass-through status and that are not otherwise addressed in section 1833(t)(14) of the Act. Some of the items for which such payment is not specified are (1) those that have been paid separately since implementation of the OPPS on August 1, 2000, but are not eligible for pass-through status, and (2) those that have historically been packaged with the procedure with which they are billed but, based on the CY 2003 claims data, their median cost per day is above the legislated $50 packaging threshold. Because Pub. L. 108–173 does not address how we are to pay for such drugs and biologicals (any drug or biological that falls into one or the other category and that has a per day cost greater than $50), we are proposing to set payment based on median costs derived from the CY 2003 claims data. Because these products are generally older or low-cost items, or

both, we believe that the proposed payments would allow us to provide adequate payment to hospitals for furnishing these items. Table 28. below lists the drugs and biologicals to which this proposed payment policy would apply.

Table 28.—List of Drugs and Biologicals Not Eligible for Pass-Through Status and Proposed for Separate Nonpass-Through Payment

HCPCS	Status Indicator	APC	Short Description	2005 Proposed Payment Rate
A4643	K	9026	High dose contrast MRI	$26.52
A4647	K	9027	Supp- paramagnetic contr mat	$37.02
J0120	K	9028	Tetracyclin injection	$101.05
J0150	K	0379	Injection adenosine 6 MG	$12.42
J0152	K	0917	Adenosine injection	$20.45
J0282	K	9029	Amiodarone HCl	$12.06
J0285	K	9030	Amphotericin B	$63.80
J0395	K	9031	Arbutamine HCl injection	$68.80
J0475	K	9032	Baclofen 10 MG injection	$8.52
J0740	K	9033	Cidofovir injection	$353.60
J0945	K	9034	Brompheniramine maleate inj	$59.63
J1051	K	9035	Medroxyprogesterone inj	$17.75
J1212	K	9036	Dimethyl sulfoxide 50% 50 ML	$52.29
J1230	K	9037	Methadone injection	$13.46
J1245	K	0380	Dipyridamole injection	$11.85
J1410	K	9038	Inj estrogen conjugate 25 MG	$39.66
J1450	K	9039	Fluconazole	$23.51
J1452	K	9040	Intraocular Fomivirsen na	$949.71
J1460	K	9041	Gamma globulin 1 CC inj	$31.96
J1610	K	9042	Glucagon hydrochloride/1 MG	$46.61
J1730	K	9043	Diazoxide injection	$15.49
J1742	K	9044	Ibutilide fumarate injection	$130.82
J1750	K	9045	Iron dextran	$14.71
J1756	K	9046	Iron sucrose injection	$0.52
J1835	K	9047	Itraconazole injection	$42.56
J2260	K	7007	Inj milrinone lactate / 5 MG	$8.06
J2597	K	9048	Inj desmopressin acetate	$4.71
J2725	K	9049	Inj protirelin per 250 mcg	$41.24
J2916	K	9050	Na ferric gluconate complex	$6.29
J2995	K	0911	Inj streptokinase /250000 IU	$43.87
J2997	K	7048	Alteplase recombinant	$17.86
J3350	K	9051	Urea injection	$70.48
J3365	K	7036	Urokinase 250,000 IU inj	$125.96
J3400	K	9052	Trifluprom azine hcl inj	$74.08
J3530	K	9053	Nasal vaccine inhalation	$93.39
J7342	K	9054	Metabolically active tissue	$7.23
J7350	K	9055	Injectable human tissue	$8.14
P9041	K	0961	Albumin (human),5%, 50ml	$19.47
P9045	K	0963	Albumin (human), 5%, 250 ml	$59.30
P9046	K	0964	Albumin (human), 25%, 20 ml	$13.16
P9047	K	0965	Albumin (human), 25%, 50ml	$55.94

e. Proposed CY 2005 Change in Payment Status for HCPCS Code J7308

Since implementation of the OPPS on August 1, 2000, HCPCS code J7308 (Aminolevulinic acid HCI for topical administration, 20 percent single unit dosage form) has been treated as a packaged item and denoted as such using status indicator ''N''. Thus, historically we have not allowed separate payment for this drug under the OPPS. In CY 2005, this drug would receive a separate payment under the Medicare physician fee schedule when furnished in a physician's office. Therefore, as we generally intend to establish, wherever possible, consistent payment policies for drugs whether they are furnished in a hospital outpatient setting or in a physician's office or clinic, we are proposing to also pay separately for J7308 when furnished in a hospital outpatient department. Thus, for CY 2005, we are proposing to pay for this drug at 106 percent of ASP, which is equivalent to the payment rate that it would receive under the physician fee schedule. The proposed CY 2005 ASP and payment under the OPPS for J7308 is $88.86. We are soliciting comments on our proposed payment methodology for HCPCS code J7308 for CY 2005.

C. Proposed Coding and Billing for Specified Outpatient Drugs

[If you choose to comment on issues in this section, include the caption ''Drug Coding and Billing'' at the beginning of your comment.]

As discussed in the January 6, 2004 interim final rule with comment period (69 FR 826), hospitals were instructed to bill for sole source drugs using the existing HCPCS code, which were priced in accordance with the provisions of newly added section 1833(t)(14)(A)(i) of the Act, as added by Pub. L. 108–173. However, at that time, the existing HCPCS codes did not allow us to differentiate payment amounts for innovator multiple source and noninnovator multiple source forms of the drug. Therefore, effective April 1, 2004, we implemented new HCPCS codes via Program Transmittal 112 (Change Request 3144, February 27, 2004) and Program Transmittal 132 (Change Request 3154, March 30, 2004) that providers were instructed to use to bill for innovator multiple source drugs in order to receive appropriate payment in accordance with section 1833(t)(14)(A)(i)(II) of the Act. Providers were also instructed to continue to use the current HCPCS codes to bill for noninnovator multiple source drugs to receive payment in accordance with section 1833(t)(14)(A)(i)(III). In this manner, drugs, biologicals, and radiopharmaceuticals will be appropriately coded to reflect their classification and be paid accordingly. We are proposing to continue this coding practice in CY 2005 with payment made in accordance with section 1833(t)(14)(A)(ii) of the Act.

D. Proposed Payment for New Drugs, Biologicals and Radiopharmaceuticals Before HCPCS Codes Are Assigned

[If you choose to comment on issues in this section, include the caption ''HCPCS Codes'' at the beginning of your comment.]

1. Background

Historically, hospitals have used a code for an unlisted or unclassified drug, biological, or radiopharmaceutical or used an appropriate revenue code to bill for drugs, biologicals, and radiopharmaceuticals furnished in the outpatient department that do not have an assigned HCPCS code. The codes for not otherwise classified drugs, biologicals, and radiopharmaceuticals are assigned packaged status under the OPPS. That is, separate payment is not made for the code, but charges for the code would be eligible for an outlier payment and, in future updates, the charges for the code are packaged with the separately payable service with which the code is reported for the same date of service.

Drugs and biologicals that are newly approved by the FDA and for which a HCPCS code has not yet been assigned by the National HCPCS Alpha-Numeric Workgroup could qualify for pass-through payment under the OPPS. An application must be submitted to CMS in order for a drug or biological to be assigned pass-through status, along with a temporary C-code for billing purposes, and an APC payment amount. Pass-through applications are reviewed on a flow basis, and payment for drugs and biologicals approved for pass-through status is implemented throughout the year as part of the quarterly updates of the OPPS.

In the November 7, 2003 final rule with comment period (68 FR 63440), we explained how CMS generally pays under the OPPS for new drugs and biologicals that are assigned HCPCS codes, but that are not approved for pass-through payment, and for which CMS had no data upon which to base a payment rate. These codes do not receive separate payment, but are assigned packaged status. Hospitals were urged to report charges for the new codes even though separate payment is not provided. Charges reported for the new codes are used to determine hospital costs and payment rates in future updates. For CY 2004, we again noted that drugs that were assigned a HCPCS code effective January 1, 2004, and that were assigned packaged status, remain packaged unless pass-through status is approved for the drug. If pass-through status is approved for these drugs, pass-through payments are implemented prospectively in the next available quarterly release.

2. Provisions of Pub. L. 108–173

Section 621(a)(1) of Pub. L. 108–173 amended section 1833(t) of the Act by adding paragraph (15) to provide for payment for new drugs and biologicals until HCPCS codes are assigned under the OPPS. Under this provision, we are required to make payment for an outpatient drug or biological that is furnished as part of covered OPD services for which a HCPCS code has not been assigned in an amount equal to 95 percent of AWP. This provision applies only to payments under the OPPS, effective January 1, 2004. However, we did not implement this provision in the January 6, 2004 interim final rule with comment period because we had not determined at that time how hospitals would be able to bill Medicare and receive payment for a drug or biological that did not have an identifying HCPCS code.

As stated earlier, at its February 2004 meeting, the APC Panel heard presentations suggesting how to make payment for a drug or biological that did not have a code. The APC Panel recommended that we work swiftly to implement a methodology to enable hospitals to file claims and receive payment for drugs that are newly approved by the FDA. The APC Panel further recommended that we consider using temporary or placeholder codes that could be quickly assigned following FDA approval of a drug or biological to facilitate timely payment for new drugs and biologicals.

We have explored a number of options to make operational the provisions of section 1833(t)(15) of the Act, as added by section 621(a)(1) of Pub. L. 108–173, as soon as possible. One of the approaches that we considered was to establish a set of placeholder codes in the Outpatient Code Editor (OCE) and the PPS pricing software for the hospital OPPS (PRICER) that we would instruct hospitals to use when a new drug was approved. Hospitals would be able to submit claims using the new code but would receive no payment until the next quarterly update. By that time, we would have installed an actual payment amount and descriptor for the code into

the PRICER, and would mass-adjust claims submitted between the date of FDA approval and the date of installation of the quarterly release. A second option that we considered was to implement an APC, a C-code, and a payment amount as part of the first quarterly update following notice of FDA approval of a drug or biological. Hospitals would hold claims for the new drug or biological until the quarterly release was implemented and then submit all claims for the drug or biological for payment using the new C-code to receive payment on a retroactive basis. We also considered instructing hospitals to bill for a new drug or biological using a ''not otherwise classified'' code for which they would receive an interim payment based on charges converted to cost. Final payment would then be reconciled at cost report settlement. While each of these approaches might enable hospitals to begin billing for a newly approved drug or biological as soon as it received FDA approval, each approach had significant operational disadvantages, such as increased burden on hospitals or payment delays, or the risk of significant overpayments or underpayments that could not be resolved until cost report settlement.

We adopted an interim approach that we believe balances the need for hospitals to receive timely and accurate payment as soon as a drug or biological is approved by the FDA with minimal disruption of the OPPS claims processing modules that support the payment of claims. On May 28, 2004 (Transmittal 188, Change Request 3287), we instructed hospitals to bill for a drug or biological that is newly approved by the FDA by reporting the National Drug Code (NDC) for the product along with a new HCPCS code C9399, Unclassified drug or biological. When C9399 appears on a claim, the OCE suspends the claim for manual pricing by the fiscal intermediary. The fiscal intermediary prices the claim at 95 percent of its AWP using Red Book or an equivalent recognized compendium, and processes the claim for payment. This approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product-specific HCPCS to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. Hospitals would discontinue billing C9399 and the NDC upon implementation of a HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. In this proposed rule, we are proposing to formalize this methodology for CY 2005 and to expand it to include payment for new radiopharmaceuticals to which a HCPCS code is not assigned (see section V.G. of this preamble). We are soliciting comments on the methodology and are particularly interested in the reaction of hospitals to using this approach to bill and receive timely payment under the OPPS for drugs, biologicals, and radiopharmaceuticals that are newly approved by the FDA, prior to assignment of a product-specific HCPCS code.

E. Proposed Payment for Vaccines

[If you choose to comment on issues in this section, include the caption ''Vaccines'' at the beginning of your comment.]

Outpatient hospital departments administer large amounts of the vaccines for influenza (flu) and pneumococcal pneumonia (PPV), typically by participating in immunization programs. In recent years, the availability and cost of some vaccines (particularly the flu vaccine) have fluctuated considerably. As discussed in the November 1, 2002 final rule (67 FR 66718), we were advised by providers that OPPS payment was insufficient to cover the costs of the flu vaccine and that access of Medicare beneficiaries to flu vaccines might be limited. They cited the timing of updates to OPPS rates as a major concern. They indicated that our update methodology, which uses 2-year-old claims data to recalibrate payment rates, would never be able to take into account yearly fluctuations in the cost of the flu vaccine. We agreed with this concern and decided to pay hospitals for influenza and pneumococcal pneumonia vaccines based on a reasonable cost methodology. As a result of this change, hospitals, home health agencies (HHAs), and hospices, which were paid for these vaccines under the OPPS in CY 2002, have been receiving payment at reasonable cost for these vaccines since CY 2003. We are aware that access concerns continue to exist for these vaccines. However, we continue to believe that payment other than on a reasonable cost basis would exacerbate existing access problems. Therefore, we are proposing to continue paying for influenza and pneumococcal pneumonia vaccines under the reasonable cost methodology in CY 2005.

F. Proposed Changes in Payment for Single Indication Orphan Drugs

[If you choose to comment on issues in this section, include the caption ''Orphan Drugs'' at the beginning of your comment.]

Section 1833(t)(1)((B)(i) of the Act gives the Secretary the authority to designate the hospital outpatient services to be covered. The Secretary has specified coverage for certain drugs as orphan drugs (section 1833(t)(14)(B)(ii)(III) of the Act as added by section 621(a)(1) of Pub. L. 108–173). Section 1833(t)(14)(C) of the Act as added by section 621(a)(1) of Pub. L. 108–173, gives the Secretary the authority in CYs 2004 and 2005 to specify the amount of payment for an orphan drug that has been designated as such by the Secretary.

We recognize that orphan drugs that are used solely for an orphan condition or conditions are generally expensive and, by definition, are rarely used. We believe that if the cost of these drugs were packaged into the payment for an associated procedure or visit, the payment for the procedure might be insufficient to compensate a hospital for the typically high cost of this special type of drug. Therefore, we are proposing to continue making separate payments for orphan drugs based on their currently assigned APCs.

In the November 1, 2002 final rule (67 FR 66772), we identified 11 single indication orphan drugs that are used solely for orphan conditions by applying the following criteria:

- The drug is designated as an orphan drug by the FDA and approved by the FDA for treatment of only one or more orphan conditions(s).
- The current United States Pharmacopoeia Drug Information (USPDI) shows that the drug has neither an approved use nor an off-label use for other than the orphan condition(s).

Eleven single indication orphan drugs were identified as having met these criteria and payments for these drugs were made outside of the OPPS on a reasonable cost basis.

In the November 7, 2003 final rule with comment period (68 FR 63452), we discontinued payment for orphan drugs on a reasonable cost basis and made separate payments for single indication orphan drugs. Payments for the orphan drugs were made at 88 percent of the AWP listed for these drugs in the April 1, 2003 single drug pricer, unless we were presented with verifiable information that shows that our payment rate does not reflect the price that is widely available to the hospital market. For CY 2004, Ceredase

(alglucerase) and Cerezyme (imiglucerase) were paid at 94 percent of AWP because external data submitted by commenters on the August 12, 2003 proposed rule caused us to believe that payment at 88 percent of AWP would be insufficient to ensure beneficiaries' access to these drugs.

In the December 31, 2003 correction of the November 7, 2003 final rule with comment period (68 FR 75442), we added HCPCS code J9017, arsenic trioxide (per unit) to our list of single indication orphan drugs. To date, the following are the 12 orphan drugs that we have identified as meeting our criteria: J0205 Injection, alglucerase, per 10 units; J0256 Injection, alpha 1-proteinase inhibitor, 10 mg; J9300 Gemtuzumab ozogamicin, 5 mg; J1785 Injection, imiglucerase, per unit; J2355 Injection, oprelvekin, 5 mg; J3240 Injection, thyrotropin alpha, 0.9 mg; J7513 Daclizumab parenteral, 25 mg; J9015 Aldesleukin, per vial; J9017 Arsenic trioxide, per unit; J9160 Denileukin diftitox, 300 mcg; J9216 Interferon, gamma 1-b, 3 million units and Q2019 Injection, basiliximab, 20 mg. We are not proposing any changes to this list of orphan drugs for CY 2005.

If we had not classified these drugs as single indication orphan drugs for payment under the OPPS, they would have met the definition and been paid as single source specified covered outpatient drugs, resulting in lower payments which could impede beneficiary access to these unique drugs dedicated to the treatment of rate diseases. Instead, for CY 2005, under our authority at section 1833(t)(14)(C) of the Act, we are proposing to pay for all 12 single indication orphan drugs, including Ceredase and Cerezyme, at the rate of 88 percent of AWP or 106 percent of the ASP, whichever is higher. However, for drugs where 106 percent of ASP would exceed 95 percent of AWP, payment would be capped at 95 percent of AWP, which is the upper limit allowed for sole source specific covered outpatient drugs. For example, Ceredase and Cerezyme would each be paid at 95 percent of the AWP because payment at 106 percent of the ASP for these two drugs not only exceeds 88 percent of the AWP but also exceeds 95 percent of the AWP. We are proposing to pay the higher of 88 percent of AWP or 106 percent of ASP capped at 95 percent of AWP to ensure that beneficiaries will continue to have access to such important drugs.

G. Proposal To Change Payment Policy for Radiopharmaceuticals

[If you choose to comment on issues in this section, include the caption ''Radiopharmaceuticals'' at the beginning of your comment.]

In the November 1, 2002 OPPS final rule (67 FR 66757), we determined that we would classify any product containing a therapeutic radioisotope to be in the category of benefits described under section 1861(s)(4) of the Act. We also determined that the appropriate benefit category for diagnostic radiopharmaceuticals is section 1861(s)(3) of the Act. We stated in the November 1, 2002 final rule that we will consider neither diagnostic nor therapeutic radiopharmaceuticals to be drugs as defined in 1861(t) of the Act (67 FR 66757). Therefore, beginning with the CY 2003 OPPS update, and continuing with the CY 2004 OPPS update, we have not qualified diagnostic or therapeutic radiopharmaceuticals as drugs or biologicals.

When we analyzed the many changes mandated by Pub. L. 108–173 that affect how we would pay for drugs, biologicals, and radiopharmaceuticals under the OPPS in CY 2005, we revisited the decision that we implemented in CY 2003 not to classify diagnostic and therapeutic radiopharmaceuticals as drugs or biologicals. In our analysis, we noted that although we did not consider radiopharmaceuticals for pass-through payment in CYs 2003 and 2004, we did apply to radiopharmaceuticals the same packaging threshold policy that we applied to other drugs and biologicals, and which we are proposing to continue in CY 2005. In addition, for the CY 2004 OPPS update, we applied the same adjustments to median costs for radiopharmaceuticals that we applied to separately payable drugs and biologicals that did not have pass-through status (68 FR 63441).

In our review of this policy, we noted that section 1833(t)(14)(B)(i) of the Act, as amended by section 621(a) of Pub. L. 108–173, does include ''radiopharmaceutical'' within the meaning of the term ''specified covered outpatient drugs,'' although neither section 621(a)(2) nor section 621(a)(3) of Pub. L. 108–173 includes a reference to radiopharmaceuticals.

In an effort to provide a consistent reading and application of the statute, we are proposing to apply to radiopharmaceuticals certain provisions in section 621 of Pub. L. 108–173 which affect payment for drugs and biologicals billed by hospitals for payment under the OPPS. We believe it is reasonable to include radiopharmaceuticals in the general category of drugs in light of their inclusion as specified covered outpatient drugs in section 1833(t)(14)(B) of the Act, as added by section 621(a)(1) of Pub. L. 108–173.

Section 621(a)(1) of Pub. L. 108–173, which amends section 1833(t) of the Act by adding a new subparagraph (14) affecting payment for radiopharmaceuticals under the OPPS, is unambiguous. This provision clearly requires that separately paid radiopharmaceuticals be classified as ''specified covered outpatient drugs.'' Therefore, in CY 2005, we propose to continue to set payment for radiopharmaceuticals in accordance with these requirements, which are discussed in detail in section V.B.3. of this preamble.

Section 1833(t)(16)(B) of the Act, as added by section 621(a)(2) of Pub. L. 108–173, requires us to reduce the threshold for the establishment of separate APCs with respect to drugs and biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006. We are proposing to apply the $50 packaging threshold methodology discussed in section V.B.2. of this preamble to radiopharmaceuticals as well as to drugs and biologicals.

Section 1833(t)(15) of the Act, added by section 621(a)(1) of Pub. L. 108–173, requires us to make payment equal to 95 percent of the AWP for an outpatient drug or biological that is covered and furnished as part of covered OPD services for which a HCPCS code has not been assigned. We propose, beginning in CY 2005, to extend to radiopharmaceuticals the same payment methodology proposed in section V.D. of this preamble for new drugs and biologicals before HCPCS codes are assigned. That is, we are proposing to pay for newly approved radiopharmaceuticals, as well as newly approved drugs and biologicals, at 95 percent of AWP prior to assignment of a HCPCS code.

Section 1833(t)(5)(E) of the Act, as added by section 621(a)(3) of Pub. L. 108–173, excludes separate drug and biological APCs from outlier payments. Beginning in CY 2005, we are proposing to apply section 621(a)(3) of Pub. L. 108–173 to APCs for radiopharmaceuticals. That is, beginning in CY 2005, radiopharmaceuticals would be excluded from receiving outlier payments.

Consistent with our proposal to apply to radiopharmaceutical agents payment policies that apply to drugs and biologicals, we further propose, beginning in CY 2005, to accept applications for pass-through status for certain radiopharmaceuticals. That is, we propose on a prospective basis to consider for pass-through status those

radiopharmaceuticals to which a HCPCS code is first assigned on or after January 1, 2005. As we explain in section V.A.3. above, section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs and biologicals as the amount determined under section 1842(o) of the Act. We propose in section V.A.3. to pay for drugs and biologicals with pass-through status in CY 2005 consistent with the provisions of section 1842(o) of the Act as amended by Pub. L. 108–173, at a rate that is equivalent to the payment these drugs and biologicals would receive in the physician office setting and set in accordance with the methodology described in the Medicare Physician Fee Schedule Proposed Rule for CY 2005 (69 FR 47488, 47520 through 47524).

We issued an interim final rule with comment period entitled "Medicare Program: Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals'' in the April 6, 2004 **Federal Register**, related to the calculation and submission of manufacturer's ASP data (69 FR 17935). We need these data in order to determine payment for drugs and biologicals furnished in a physician office setting in accordance with the methodology described in the Medicare Physician Fee Schedule Proposed Rule (69 FR 47488, 47520 through 47524). However, the April 6, 2004 interim final rule with comment period excludes radiopharmaceuticals from the data reporting requirements that apply to Medicare Part B covered drugs and biologicals paid under sections 1842(o)(1)(D), 1847A, or 1881(b)(13)(A)(ii) of the Act (69 FR 17935). As a consequence, we would not have the same type of data available to determine payment for a new radiopharmaceutical approved for pass-through status after January 1, 2005 that would be available to determine payment for a new drug or biological with pass-through status in CY 2005.

Therefore, in order to set payment for a new radiopharmaceutical approved for pass-through status in accordance with 1842(o) and in a manner that is consistent with how we propose to set payment for a pass-through drug or biological, we are proposing a methodology that would apply solely to new radiopharmaceuticals for which payment would be made under the OPPS and for which an application for pass-through status is submitted after January 1, 2005. That is, in order to receive pass-through payment for a new radiopharmaceutical under the OPPS, a manufacturer would be required to submit data and certification for the radiopharmaceutical in accordance with the requirements that apply to drugs and biologicals under section 303 of Pub. L. 108–173 as set forth in the interim final rule with comment period issued in the April 6, 2004 **Federal Register** (66 FR 17935) and described on the CMS website at *cms.hhs.gov.* Payment would be determined in accordance with the methodology applicable to drugs and biologicals that is discussed in the CY 2005 Medicare Physician Fee Schedule proposed rule (69 FR 47488, 47520–47524). In the event the manufacturer seeking pass-through status for a radiopharmaceutical does not submit data in accordance with the requirements specified for new drugs and biologicals, we propose to set payment for the new radiopharmaceutical as a specified covered outpatient drug, under section 1833(t)(14)(A) as added by section 621(a)(1) of Pub. L. 108–173.

H. Proposed Coding and Payment for Drug Administration

[If you choose to comment on issues in this section, include the caption "Drug Administration'' at the beginning of your comment.]

Since implementation of the OPPS, Medicare OPPS payment for administration of cancer chemotherapy drugs and infusion of other drugs has been made using the following HCPCS codes:

- Q0081, Infusion therapy other than chemotherapy, per visit
- Q0083, Administration of chemotherapy by any route other than infusion, per visit
- Q0084, Administration of chemotherapy by infusion only, per visit
- Q0085, Administration of chemotherapy by both infusion and another route, per visit

In the CY 2004 proposed rule, we proposed to change coding and payment for these services to enable us to pay more accurately for the wide range of services and the drugs that we package into these per visit codes. (See August 12, 2003 proposed rule (68 FR 47998) for background discussion on these codes.) Commenters on the CY 2004 proposed rule recommended that we use the CPT codes for drug administration. One commenter provided a crosswalk from the CPT codes for drug administration to the Q codes that we could use in a transition. We did not implement this in the final rule for CY 2004 OPPS but indicated that we would consider it for CY 2005 and would discuss it with the APC Panel at its February 2004 meeting.

Commenters and the APC Panel recommended that we discontinue use of code Q0085 for CY 2004 because codes Q0083 and Q0084 could be used together to report the services described by code Q0085. We did implement this change for CY 2004 and made code Q0085 nonpayable for CY 2004 OPPS.

At the APC Panel meeting, we presented a proposal from an outside organization that matched CPT codes for chemotherapy and nonchemotherapy infusions to the Q codes currently used to pay for these services under the OPPS. We asked the APC Panel for their perspective on the potential benefit of using the proposed coding approach as the basis for billing and determining OPPS payment for administering these drugs. The APC Panel recommended that CMS continue to review the organization's proposed coding crosswalk with the goal of using it to transition from the use of Q codes to that of CPT codes to bill for administration of these drugs.

For CY 2005, we are proposing to use the CPT codes for drug administration but to crosswalk the CPT codes into APCs that reflect how the services would have been paid under the Q codes. Although hospitals would bill the CPT codes and include the charges for each CPT code on the claim, payment would be made on a per visit basis, using the cost data from the per visit Q codes (Q0081, Q0083 and Q0084) to set the payment rate for CY 2005. See Table 29. for the crosswalk of CPT codes into APCs based on the Q codes. The only change from the crosswalk that was submitted by the outside organization is that we are proposing a Q code and APC crosswalk for CPT code 96549 (Unlisted chemotherapy procedure), rather than bundling that service. We believe that Q0083 is the code that would have previously been reported by hospitals to describe the unlisted service. In addition, this would place the unlisted service in our lowest resource utilization APC for chemotherapy, consistent with our policy for other unlisted services.

We are proposing to establish the Q code and APC crosswalk for CPT code 96549 because there is no CPT specific charge or frequency data on which to set payments. The CY 2005 OPPS is based on CY 2003 claims data which used the Q codes. Therefore, the only cost data available to us for establishment of median costs is the data based on the Q codes for drug administration. Moreover, the only frequency data that are available for use in calculating the scaler for budget neutrality of payment weights are the frequency data for the Q

codes. Therefore, the payments set for the CPT codes must use the cost data for the Q codes and must result in the same payments that would have been made had the Q codes been continued.

Under this proposed methodology, hospitals would report the services they furnish with the CPT codes and would show the charges that they assign to the CPT codes on the claim. The Medicare OCE would assign the code to an APC whose payment is based on the per visit Q code that would have been used absent coding under CPT. In most cases, the OCE would collapse multiple codes or multiple units of the same CPT code into a single unit to be paid a single APC amount. This approach is needed because the data for the Q codes is reported on a per visit basis and more than one unit of a CPT code can be provided in a visit.

For example, CPT code 96410 (Chemotherapy administration infusion technique, up to 1 hour) is for infusion of chemotherapy drugs for the first hour, and CPT code 96412 is for chemotherapy infusion up to 8 hours, each additional hour. The claims data used to set the APC payment rate for these codes is for a per visit amount (taken from CY 2003 data for Q0084 a per visit code). The frequency data on the claim are also on a per visit basis. For CY 2005, we are proposing that CPT code 96410 would be paid one unit of APC 0117 (to which CPT code 96410 would be crosswalked) and no separate payment would be made for CPT code 96412, regardless of whether one unit or more than one unit is billed. CPT code 96412 would be a packaged code for CY 2005. Under the Q code data on which the payment weight for APC 0117 is based, the per visit amount would represent a payment that is appropriate for all drug administration services in a visit (that is, one unit of CPT code 96410 and as many units of CPT code 96412 as were furnished in the same visit).

Similarly, when a hospital bills 3 units of 96400 (Chemotherapy administration, subcutaneous or intramuscular, with or without local anesthesia), the OCE would assign one unit of APC 0116 for that code. (APC 0116 is the APC to which CPT code 96400 would be crosswalked.) The payment would be based on Q0083, a per visit code, because, absent the ability to be paid based on CPT codes, the hospital would have billed one unit of Q0083 (for the 3 injections) had we not discontinued the Q codes for CY 2005. The OCE would assume that there was one and only one visit in which there were 3 injections and would pay accordingly (that is, one unit of APC 0116).

If we adopt the CPT codes for drug administration to ensure accurate payment in the future, it would be critical for hospitals to bill the charges for the packaged CPT codes for drug administration for CY 2005 (that is, the CPT codes with SI=N), even though there would be no separate payment for them in CY 2005. For CY 2007 OPPS, CY 2005 claims data would be used as the basis for setting median costs for each CPT code, based on the reported charges reduced to cost, and would determine what APC configuration ensures most appropriate payment for the CPT drug administration codes. If hospitals do not bill charges in CY 2005 for the packaged drug administration CPT codes such as CPT codes 96412, 96423, 96545, or 90781, they would jeopardize our ability to make accurate payments for services billed and paid under these codes in CY 2007 when we use the CY 2005 data to set the payment weights.

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Table 29.--Proposed Crosswalk from CPT Codes for Drug Administration to Drug Administration APCs

CPT Code	Description	Proposed SI	Proposed APC	Corresponding HCPCS code	Maximum units of the APC OCE would assign, regardless of codes billed
96400	Chemotherapy, sc/im	S	116	Q0083	1
96405	Intralesional chemo admin	S	116	Q0083	1
96406	Intralesional chemo admin	S	116	Q0083	1
96408	Chemotherapy, push technique	S	116	Q0083	1
96410	Chemotherapy,infusion method	S	117	Q0084	1
96412	Chemo, infuse method add-on	N	--	--	0
96414	Chemo, infuse method add-on	S	117	Q0084	1
96420	Chemotherapy, push technique	S	116	Q0083	1
96422	Chemotherapy,infusion method	S	117	Q0084	1
96423	Chemo, infuse method add-on	N	--	--	0
96425	Chemotherapy,infusion method	S	117	Q0084	1
96440	Chemotherapy, intracavitary	S	116	Q0083	1
96445	Chemotherapy, intracavitary	S	116	Q0083	1
96450	Chemotherapy, into CNS	S	116	Q0083	1
96542	Chemotherapy injection	S	116	Q0083	1
96545	Provide chemotherapy agent	N	--	--	0
96549	Chemotherapy, unspecified	S	116	Q0083	1
90780	IV infusion therapy, 1 hour	T	120	Q0081	1
90781	IV infusion, additional hour	N	--	--	0

I. Proposed Payment for Blood and Blood Products

[If you choose to comment on issues in this section, include the caption "Blood and Blood Products'' at the beginning of your comments.]

Since the OPPS was first implemented in August 2000, separate payment has been made for blood and blood products in APCs rather than packaging them into payment for the procedures with which they were administered. We recognize that blood is a valuable health care resource used regularly in a broad range of hospital procedures and the availability of safe blood is essential to the delivery of high quality health care services to Medicare beneficiaries.

In CY 2000, payment for blood was established based on external data provided by commenters due to limited Medicare claims data. From CY 2000 to CY 2002, payment rates were updated for inflation. For CY 2003, as described in the November 1, 2002 final rule (67 FR 66773), we applied a special dampening methodology to blood and blood products that had significant reductions in payment rates from CY 2002 to CY 2003. Using the dampening methodology, we limited the decrease in

payment rates for blood and blood products to approximately 15 percent. For CY 2004, as recommended by the APC Panel, we froze payment rates for blood and blood products at CY 2003 levels. This allowed us to undertake further study of the issues raised by past commenters and presenters at the August 2003 and February APC 2004 Panel meetings.

For CY 2005, we are proposing to continue to pay separately for blood and blood products. We also are proposing to establish new APCs that would allow each blood product to be in its own separate APC. In addition, after review, we determined that several of the blood product APCs contained multiple blood products with no clinical homogeneity or whose product-specific median costs may not have been similar. Thus, we are also proposing to reassign some of these HCPCS already contained in certain APCs to new APCs. Table 30 below lists, by HCPCS code, our proposed CY 2005 APC reassignments for such blood and blood products.

Table 30.--Proposed Assignment of Blood and Blood Product Codes to APCs for CY 2005

HCPCS	Expired HCPCS	Status Indicator	Description	APC
P9023		K	Frozen plasma, pooled, sd	0949
P9054	C1016	K	Blood, L/R, Froz/Degly/Washed	1016
P9036		K	Platelet pheresis irradiated	9502
P9039		K	RBC deglycerolized	9504
P9052	C1011	K	Platelets, HLA-m, L/R, unit	1011
P9048		K	Plasmaprotein fract,5%,250ml	0966
P9055	C1017	K	Plt, Aph/Pher, L/R, CMV-Neg	1017
P9060	C9503	K	Fresh frozen plasma, ea unit	9503
P9043		K	Plasma protein fract,5%,50ml	0956
P9050		K	Granulocytes, pheresis unit	9506
P9059	C1022	K	Plasma, frz within 24 hour	0955
P9058	C1021	K	RBC, L/R, CMV neg, irradiated	1022
P9057	C1020	K	RBC, frz/deg/wsh, L/R, irradiated	1021
P9016		K	RBC leukocytes reduced	0954
P9021		K	Red blood cells unit	0959
P9019		K	Platelets, each unit	0957
P9040		K	RBC leukoreduced irradiated	0969
P9017		K	Plasma 1 donor frz w/in 8 hr	9508
P9035		K	Platelet pheres leukoreduced	9501
P9031		K	Platelets leukocytes reduced	1013
P9034		K	Platelets, pheresis	9507
P9037		K	Plate pheres leukoredu irradiated	1019
P9056	C1018	K	Blood, L/R, Irradiated	1018

HCPCS	Expired HCPCS	Status Indicator	Description	APC
P9010		K	Whole blood for transfusion	0950
P9012		K	Cryoprecipitate each unit	0952
P9033		K	Platelets leukoreduced irradiated	0968
P9051	C1010	K	Blood, L/R, CMV-NEG	1010
P9044		K	Cryoprecipitate reduced plasma	1009
P9038		K	RBC irradiated	9505
P9022		K	Washed red blood cells unit	0960
P9020		K	Plaelet rich plasma unit	0958
P9032		K	Platelets, irradiated	9500
P9011		K	Split unit of blood	0967
P9053	C1015	K	Plt, pher, L/R, CMV, irradiadted	1020

Administrative costs for the processing and storage specific to the transfused blood product are included in the APC payment, which is based on hospitals' charges. Payment for the collection, processing, and storage of autologous blood, as described by CPT 86890 and used in transfusion is made through APC 347 (Level III Transfusion Laboratory Procedures).

Other than for autologous blood products, the costs for collection, processing, storage, wastage, and other administrative costs for blood products that are not transfused are reported in the appropriate cost centers on hospitals' cost reports. These reported costs are attributable to overhead and distributed across all hospital services linked to those cost centers through the standard process of converting charges to costs using hospitals' CCRs for each cost center on the cost report.

The DHHS Advisory Committee on Blood Safety and Availability has recommended that CMS establish payment rates for blood and blood products based on current year acquisition costs and actual total costs of providing such blood products. At the February 2004 APC Panel meeting, the APC Panel recommended that CMS use external data to derive costs of blood and blood products in order to establish payment rates.

As with all services, we prefer to rely on our claims data whenever possible. We conducted a thorough analysis of billing for blood in CY 2003 claims data. Comments received for previous rules suggest that current hospital blood costs are not captured because hospitals underreport blood on their claims. Commenters explained that hospitals sometimes found it too costly to bill for blood. However, we found that 81 percent of all hospitals included in our ratesetting and modeling billed at least one blood and blood product in CY 2003. Of these hospitals, only 47 percent reported separate costs and charges in the two cost centers specific to blood on their most recent annual cost report. It may be that those hospitals billing for blood but not reporting costs and charges on their cost report for either of the two blood-specific cost centers report their blood costs and charges under other cost centers, such as operating room.

We have also received comments that the CCRs that we use to adjust claim charges to costs for blood are too low, which results in an underestimation of the true cost of blood and blood products. Our current methodology for matching cost center CCRs to revenue codes includes a default to the overall CCR when any given provider has chosen not to report costs and charges for a specific cost center. After matching the two blood-specific cost centers to the 38X and 39X revenue codes, we observed a significant difference in CCRs for those hospitals with and without blood-specific cost centers. The median CCR for those hospitals with a blood-specific cost center was 0.66 for revenue code 38X and 0.64 for revenue code 39X, and for those defaulting to the overall CCR, the result was a CCR of 0.34 for revenue code 38X and 0.33 for revenue code 39X. The median overall CCR for all hospitals in the 2005 analysis was 0.33.

As noted above, about half of the hospitals (47 percent) reported at least one of the blood-specific cost centers on their most recent cost report. We then looked at the CY 2003 claims being used to set CY 2005 median costs and discovered that about one-quarter relied on a CCR that was based on a blood-specific cost center to adjust charges to costs, and about three-quarters did not. This pattern existed even though almost all hospitals were billing blood in the 38X and 39X revenue codes. The result was the default CCR was used to adjust almost 75 percent of the line-items used to set the median costs for blood and blood products.

In light of this information, we simulated a blood-specific CCR for those hospitals now defaulting to the overall CCR. We assumed that those hospitals not reporting costs and charges in a blood-specific cost center on their annual cost report, in general, face similar costs and engage in comparable charging practices for blood as those reporting a blood-specific cost center. For each hospital reporting costs and charges for the blood cost centers on their cost report, we calculated the ratio of the CCR in the blood-specific cost center to the overall CCR. We then calculated the geometric mean of this ratio. This was 2.2 for revenue code 38X

and 2.1 for revenue code 39X. For each hospital not reporting costs and charges for the blood cost centers on their cost report, we applied this mean ratio to their overall CCR. We believe that this approach better responds to a missing blood-specific CCR than simply using the average blood-specific CCR for each revenue code because it takes into account the unique charging structure of each provider. We then adjusted charges to costs for all hospitals and calculated a median cost for all blood products. Overall, this methodology increased the estimated median costs by 25 percent for CY 2005 relative to the medians used to set CY 2004 rates. For example, the estimated median for P9016 (Red blood cells, leukocytes reduced), the most frequently billed blood product, increased by 32 percent relative to the CY 2004 median.

In reviewing the simulated medians created above relative to those medians used to set CY 2004 payment rates, we noticed that procedures relying on a low volume of blood units (<1,000) demonstrated large decreases. Overall, the simulated median costs for low-volume blood products declined by 14 percent for CY 2005. Because a small sample size can lead to great variability in point estimates, we sought to increase the number of units of blood by combining CY 2002 and CY 2003 claims data for the low-volume products. We used the simulated CCRs to calculate costs from charges. We recognize that not all of the low-volume blood products had claims in CY 2002. Listed in Table 31 are the low volume products for which we combined CY 2002 and 2003 claims. To ensure that we combined comparable costs, we updated the simulated costs on the claims in CY 2002 to the base year of 2003 using the Producer Price Index (PPI) for blood and derivatives for human use (Commodity Code #063711), which is the PPI used to update blood and blood product prices in the market basket (67 FR 50039, August 1, 2002). We estimated the annual PPI from December 2002 to December 2003 to be −12.2 percent. Although a decline in PPI is unusual, we understand that the price of plasma products have recently declined. Further, the majority of the low-volume items are plasma products. After combining the 2 years of claims, we were able to raise the volume of blood units billed for 5 of these products above 1,000. Ultimately, overall estimated median costs continue to increase by 25 percent for all products, but decline by 16 percent for the low-volume products.

Table 31.—Low Volume Proposed Blood and Blood Products Codes for CY 2005 Payments

HCPCS	Description
P9023	Frozen plasma, pooled, sd
P9054	Blood, leukocyte reduced, frozen, deglycerolized, washed
P9036	Platelet pheresis irradiated
P9039	Red blood cells deglycerolized
P9052	Platelets, HLA-m, leukocyte reduced, unit
P9048	Plasmaprotein fractionated, 5 percent, 250 ml
P9055	Platelet, APH/PHER, leukocyte reduced, CMV, irradiated
P9060	Fresh frozen plasma, each unit
P9043	Plasma protein fractionated, 5 percent, 50 ml
P9050	Granulocytes, pheresis unit

After discussions with industry representatives and hospitals and careful consideration of our claims analyses, for CY 2005 we are proposing to set payment rates for all blood and blood products listed in Table 29 based on our CY 2003 claims data, utilizing an actual or simulated hospital blood-specific CCR to convert charges to costs for blood and blood products. For those low-volume products listed in Table 30, we would combine claims data for CYs 2002 and 2003. We are confident that we have claims data from the vast majority of the OPPS hospitals for blood products, and the tight distribution of costs for individual products, including low-volume products, provides no evidence of significant coding problems. In general, as a blood product undergoes increasing levels of processing or selection, our CY 2005 proposed payment for the product would increase commensurate with the additional resources utilized. We believe that the proposed payment methodology described above will enable us to use our historical hospital claims data to assure the adequate payment for blood and blood products essential to continued Medicare beneficiary access to blood and blood products. In addition, we recognize the need to clarify billing regarding a variety of blood-related services under the OPPS in response to numerous questions and comments we have received. We intend to provide further billing guidelines to clarify our original Program Transmittal A–01–50 issued on April 12, 2001 (CR Request 1585) regarding correct billing for blood-related services in the near future.

VI. Estimated Transitional Pass-Through Spending in CY 2005 for Drugs, Biologicals, and Devices

[If you choose to comment on issues in this section, please include the caption "Estimated Transitional Pass-Through Spending'' at the beginning of your comment.]

A. Basis for Pro Rata Reduction

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for a

given year to an ''applicable percentage'' of projected total Medicare and beneficiary payments under the hospital OPPS. For a year before CY 2004, the applicable percentage is 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 prospective 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 devices, making an estimate of pass-through spending in CY 2005 entails estimating spending for two groups of items. The first group consists of those items for which we have claims data for procedures that we believe used devices which were eligible for pass-through status in CY 2003 and CY 2004 and that would continue to be eligible for pass-through payment in CY 2005. The second group consists of those items for which we have no direct claims data, that is, items that became, or would become, eligible in CY 2004 and would retain pass-through status in CY 2005, as well as items that would be newly eligible for pass-through payment beginning in CY 2005.

B. Proposed Estimate of Pass-Through Spending for CY 2005

We are proposing to set the applicable percentage cap at 2.0 percent of the total OPPS projected payments for CY 2005. To estimate CY 2005 pass-through spending for device categories in the first group described above, we are proposing to use volume information from CY 2003 claims data for procedures associated with a pass-through device and manufacturer's price information from applications for pass-through status. This information would be projected forward to CY 2005 levels, using inflation and utilization factors based on total growth in Medicare Part B as projected by the CMS Office of the Actuary (OACT).

To estimate CY 2005 pass-through spending for device categories included in the second group, that is, items for which we have no direct claims data, we are proposing to use the following approach: For categories with no claims data in CY 2003 that would be active in CY 2005, we would follow the methodology described in the November 2, 2001 final rule (66 FR 55857). That is, we are proposing to use price information from manufacturers and volume estimates based on claims for procedures that would most likely use the devices in question. This information would be projected forward to CY 2005 using the inflation and utilization factors supplied by the CMS OACT to estimate CY 2005 pass-through spending for this group of device categories. For categories that become eligible in CY 2005, we would use the same methodology. We anticipate that any new categories for January 1, 2005, would be announced after the publication of this proposed rule but before the publication of the final rule. Therefore, the estimate of pass-through spending would incorporate pass-through spending for categories made effective January 1, 2005.

With respect to CY 2005 pass-through spending for drugs and biologicals, as we explain in section V.A.3. of this proposed rule, the pass-through payment amount for new drugs and biologicals that we determine have pass-through status would equal zero. Therefore, our estimate of total pass-through spending for drugs and biologicals with pass-through status in CY 2005 would equal zero.

Table 32.--Estimates for CY 2005 Transitional Pass-Through Spending for Current Pass-through Categories Continuing Into CY 2005

New HCPCS	APC	Existing Pass-Through Devices	CY 2005 Estimated Utilization	CY 2005 Anticipated Pass-through Payments
C1814	1814	Retinal tamponade device, silicone oil	30,576	$11,888,143
C1818	1818	Integrated keratoprosthesis device	4	27,800
C1819	1819	Tissue localization excision device	9,709	1,796,165

In accordance with the methodology described above, we estimate that total pass-through spending in CY 2005 would equal approximately $30.8 million, which represents 0.13 percent of total OPPS projected payments for CY 2005. This figure includes estimates for the current device categories continuing into CY 2005, in addition to projections for categories that first become eligible in CY 2005. This estimate is significantly lower than previous year's estimates because of the method we are proposing in section V.A.3 of this preamble for determining the amount of pass-through payment for drugs and biologicals with pass-through status in CY 2005.

In section V.G., we are proposing to accept pass-through applications for new radiopharmaceuticals that are

assigned a HCPCS code on or after January 1, 2005. The pass-through amount for new radiopharmaceuticals approved for pass-through status in CY 2005 would be the difference between the OPD payment for the radiopharmaceutical, that is, the payment amount determined for the radiopharmaceutical as a sole source specified covered drug, and the payment amount for the radiopharmaceutical under section 1842(o) of the Act. However, we have no information identifying new radiopharmaceuticals to which a HCPCS code might be assigned after January 1, 2005 for which pass-through status would be sought. We also have no data regarding payment for new radiopharmaceuticals with pass-through status under the methodology that we propose in section V.G. However, we do not believe that pass-through spending for new radiopharmaceuticals in CY 2005 would be significant enough to materially affect our estimate of total pass-through spending in CY 2005. Therefore, we are not including radiopharmaceuticals in our estimate of pass-through spending in CY 2005.

Because we estimate pass-through spending in CY 2005 would amount to 0.13 percent of total projected OPPS CY 2005 spending, we are proposing to return 1.87 percent of the pass-through pool to adjust the conversion factor, as we discuss in section VIII of this preamble.

VII. Other Policy Decisions and Proposed Policy Changes

A. Statewide Average Default Cost-to-Charge Ratios

[If you choose to comment on issues in this section, include the caption "Cost-to-Charge Ratios'' at the beginning of your comment.]

CMS uses cost-to-charge ratios (CCRs) to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS. Some hospitals do not have a valid CCR. These hospitals include, but are not limited to, hospitals that are new and have not yet submitted a cost report, hospitals that have a CCR that falls outside predetermined floor and ceiling thresholds for a valid CCR, or hospitals that have recently given up their all-inclusive rate status. When OPPS was first implemented in CY 2000, we used CY 1996 and CY 1997 cost reports to calculate default urban and rural CCRs for each State to use in determining the reasonable cost-based payments for those hospitals without a valid CCR (Program Memorandum A–00–63, CR 1310, issued on September 8, 2000). We are proposing to update the default ratios for CY 2005. Table 33 lists the proposed CY 2005 default urban and rural CCRs by State.

We calculated the proposed statewide default CCRs in Table 33 using the same CCRs that we use to adjust charges to costs on claims data. These CCRs are the ratio of total costs to total charges from each provider's most recently submitted cost report, for those cost centers relevant to outpatient services. We also adjust these ratios to reflect final settled status by applying the differential between settled to submitted costs and charges from the most recent pair of settled to submitted cost reports. The majority of submitted cost reports, 87 percent, were for CY 2002. We only used valid CCRs to calculate these default ratios. That is, we removed the CCRs for all-inclusive hospitals, CAHs, and hospitals in Guam and the U.S. Virgin Islands because these entities are not paid under the OPPS, or in the case of all-inclusive hospitals, because their CCRs are suspect. We further identified and removed any obvious error CCRs and trimmed any outliers. We limited the hospitals used in the calculation of the default CCRs to those hospitals that billed for services under the OPPS during CY 2003.

Finally, we calculated an overall average CCR, weighted by a measure of volume, for each State except Maryland. This measure of volume is the total lines on claims and is the same one that we use in our impact tables. Calculating a rate for Maryland presented a unique challenge. There are only a few providers in Maryland that are eligible to receive payment under the OPPS. However, we had no usable in-house cost report data for these Maryland hospitals. Therefore, we obtained data from the fiscal intermediary for Maryland which we attempted to use in calculating the CCRs for Maryland but which we ultimately determined could not be used to calculate representative CCRs. The cost data for 3 Maryland hospitals with very low volumes of services and cost data were so irregular that we lacked confidence that it would result in a valid statewide CCR. Thus, for Maryland, we used an overall weighted average CCR for all hospitals in the nation to calculate the weighted average CCRs appearing in Table 33. The overall decrease in default statewide CCRs can be attributed to the general decline in the ratio between costs and charges widely observed in the cost report data.

Table 33.--Statewide Average Cost-to-Charge Ratios

State	Urban/Rural	Previous Default CCR	Proposed Default CCR
Alabama	RURAL	0.31552	0.26715
Alabama	URBAN	0.29860	0.24577
Alaska	RURAL	0.59388	0.61859
Alaska	URBAN	0.38555	0.42717
Arizona	RURAL	0.39748	0.32769
Arizona	URBAN	0.30922	0.26980
Arkansas	RURAL	0.35936	0.31754
Arkansas	URBAN	0.38278	0.30471
California	RURAL	0.40335	0.29314
California	URBAN	0.32427	0.24213
Colorado	RURAL	0.51041	0.43069
Colorado	URBAN	0.41863	0.32179
Connecticut	RURAL	0.42702	0.47250
Connecticut	URBAN	0.46592	0.44626
Delaware	RURAL	0.36289	0.36304
Delaware	URBAN	0.45061	0.45948
District of Columbia	URBAN	0.38690	0.37513
Florida	RURAL	0.31782	0.24304
Florida	URBAN	0.28363	0.22401
Georgia	RURAL	0.39829	0.33823
Georgia	URBAN	0.40262	0.32105
Hawaii	RURAL	0.44420	0.41027
Hawaii	URBAN	0.34815	0.34474
Idaho	RURAL	0.49682	0.46454
Idaho	URBAN	0.51942	0.49178
Illinois	RURAL	0.41825	0.34063
Illinois	URBAN	0.36825	0.29964
Indiana	RURAL	0.44596	0.36862
Indiana	URBAN	0.44205	0.37237
Iowa	RURAL	0.50166	0.41996
Iowa	URBAN	0.46963	0.38788
Kansas	RURAL	0.48065	0.38973
Kansas	URBAN	0.34698	0.29271
Kentucky	RURAL	0.36987	0.31089

State	Urban/Rural	Previous Default CCR	Proposed Default CCR
Kentucky	URBAN	0.37381	0.32476
Louisiana	RURAL	0.34317	0.29912
Louisiana	URBAN	0.34357	0.27736
Maine	RURAL	0.47857	0.38801
Maine	URBAN	0.54084	0.44897
Massachusetts	URBAN	0.44439	0.38812
Michigan	RURAL	0.44890	0.39418
Michigan	URBAN	0.41143	0.37428
Minnesota	RURAL	0.48514	0.47136
Minnesota	URBAN	0.45259	0.37416
Mississippi	RURAL	0.34264	0.30290
Mississippi	URBAN	0.37097	0.29322
Missouri	RURAL	0.42187	0.34160
Missouri	URBAN	0.38128	0.31081
Montana	RURAL	0.51173	0.47891
Montana	URBAN	0.49396	0.44817
Nebraska	RURAL	0.49386	0.42378
Nebraska	URBAN	0.42043	0.33875
Nevada	RURAL	0.42878	0.50623
Nevada	URBAN	0.22854	0.22333
New Hampshire	RURAL	0.50083	0.43585
New Hampshire	URBAN	0.39954	0.33224
New Jersey	URBAN	0.49024	0.34038
New Mexico	RURAL	0.44932	0.33899
New Mexico	URBAN	0.50857	0.43311
New York	RURAL	0.52062	0.43944
New York	URBAN	0.54625	0.42556
North Carolina	RURAL	0.37776	0.35416
North Carolina	URBAN	0.42726	0.38114
North Dakota	RURAL	0.52829	0.41175
North Dakota	URBAN	0.47341	0.36740
Ohio	RURAL	0.42562	0.41161
Ohio	URBAN	0.42718	0.32814
Oklahoma	RURAL	0.40628	0.32908
Oklahoma	URBAN	0.36264	0.29193
Oregon	RURAL	0.47915	0.42468
Oregon	URBAN	0.49958	0.43762
Pennsylvania	RURAL	0.40582	0.36015

State	Urban/Rural	Previous Default CCR	Proposed Default CCR
Pennsylvania	URBAN	0.33807	0.28011
Puerto Rico	URBAN	0.42208	0.41376
Rhode Island	URBAN	0.43930	0.35106
South Carolina	RURAL	0.35996	0.29377
South Carolina	URBAN	0.36961	0.29167
South Dakota	RURAL	0.49599	0.39218
South Dakota	URBAN	0.44259	0.33947
Tennessee	RURAL	0.36663	0.30294
Tennessee	URBAN	0.36464	0.28313
Texas	RURAL	0.41763	0.33642
Texas	URBAN	0.33611	0.30306
Utah	RURAL	0.49748	0.47097
Utah	URBAN	0.46733	0.45230
Vermont	RURAL	0.47278	0.46757
Vermont	URBAN	0.54533	0.44259
Virginia	RURAL	0.39408	0.33502
Virginia	URBAN	0.38604	0.32559
Washington	RURAL	0.54246	0.43429
Washington	URBAN	0.54658	0.41362
West Virginia	RURAL	0.42671	0.35073
West Virginia	URBAN	0.45616	0.40700
Wisconsin	RURAL	0.50126	0.42304
Wisconsin	URBAN	0.46268	0.38487
Wyoming	RURAL	0.54596	0.51581
Wyoming	URBAN	0.41265	0.41087

B. Transitional Corridor Payments: Technical Change

[If you choose to comment on issues in this section, include the caption ''Transitional Corridor Payments'' at the beginning of your comment.]

When the OPPS was implemented, every provider was eligible to receive an additional payment adjustment (or transitional corridor payment) if the payments it received under the OPPS were less than the payment it would have received for the same services under the prior reasonable cost-based system (section 1833(t)(7) of the Act). Transitional corridor payments were intended to be temporary payments for most providers but permanent payments for cancer and children's hospitals to ease their transition from the prior reasonable cost-based payment system to the prospective payment system. Section 411 of Pub. L. 108–173 amended section 1833(t)(7)(D)(i) to the Act to extend such payments through December 31, 2005, for rural hospitals with 100 or fewer beds and extended such payments for services furnished during the period that begins with the provider's first cost reporting period beginning on or after January 1, 2004 and ends on December 31, 2005, for sole community hospitals located in rural areas. Accordingly, transitional corridor payments are only available to children's hospitals, cancer hospitals, rural hospitals having 100 or fewer beds, and sole community hospitals located in rural areas.

At the time the OPPS was implemented, section 1833(t)(7)(F)(ii) of the Act defined the payment-to-cost ratio (PCR) used to calculate the ''pre-BBA amount'' [2] for purposes of calculating the transitional corridor payments to be determined using the payments and reasonable costs of services furnished during the provider's cost reporting period ending in calendar year 1996. The BIPA, Pub. L. 106–554, enacted on December 21, 2000, revised that requirement. Section 403 of BIPA amended section 1833(t)(7)(F)(ii)(I) of the Act to allow transitional corridor payments to hospitals subject to the OPPS that did not have a 1996 cost report by authorizing use of the first available cost reporting period ending after 1996 and before 2001 in calculating a provider's PCR.

Although we discussed the BIPA amendment in the CY 2002 OPPS

[2] Section 1833(t)(7) of the Act defined the ''pre-BBA'' amount for a period as the amount equal to the product of (1) the payment-to-cost ratio for the hospital based on its *cost reporting period ending in 1996*, and (2) the reasonable cost of the services for the period. (Emphasis added.) In this context, BBA refers to the Balanced Budget Act of 1997, Pub. L. 105–33, enacted on August 5, 1997.

proposed rule published on August 24, 2001 (66 FR 44674), and implemented the amendment through Program Memorandum No. A–01–51, issued on April 13, 2001, we failed to revise the regulations at § 419.70(f)(2) to reflect the change. In this proposed rule, we are proposing a technical correction to § 419.70(f)(2) to conform it to the provision of section 1833(t)(7)(F)(ii)(I) of the Act.

C. Status Indicators and Comment Indicators Assigned in the Outpatient Code Editor (OCE)

[If you choose to comment on issues in this section, include the caption "Status Indicators and Comment Indicators'' at the beginning of your comment.]

1. Payment Status Indicators

The payment status indicators (SIs) that we assign to HCPCS codes and APCs under the OPPS play an important role in determining payment for services under the OPPS because 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. For CY 2005, we are providing our proposed status indicator (SI) assignments for APCs in Addendum A, for the HCPCS codes in Addendum B, and the definitions of the status indicators in Addendum D1 to this proposed rule.

Payment under the OPPS is based on HCPCS codes for medical and other health services. These codes are used for a wide variety of payment systems under Medicare, including, but not limited to, the Medicare fee schedule for physician services, the Medicare fee schedule for durable medical equipment and prosthetic devices, and the Medicare clinical laboratory fee schedule. For purposes of making payment under the OPPS, we must be able to signal the claims processing system through the Outpatient Code Editor (OCE) software, as to HCPCS codes that are paid under the OPPS and those codes to which particular OPPS payment policies apply. We accomplish this identification in the OPPS through the establishment of a system of status indicators with specific meanings. Addendum D1 contains the proposed definitions of each status indicator for purposes of the OPPS for CY 2005.

We assign one and only one status indicator to each APC and to each HCPCS code. Each HCPCS code that is assigned to an APC has the same status indicator as the APC to which it is assigned.

Specifically, for CY 2005, we are proposing to use the following status indicators in the specified manner:

- "A'' to indicate services that are paid under some payment method other than OPPS, such as under the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) fee schedule or the physician fee schedule. Some, but not all, of these other payment systems are identified in Addendum D1 to this proposed rule.
- "B'' to indicate the services that are not payable under the OPPS when submitted on an outpatient hospital Part B bill type, but that may be payable by fiscal intermediaries to other provider types when submitted on an appropriate bill type.
- "C'' to indicate inpatient services that are not payable under the OPPS.
- "D'' to indicate a code that is discontinued, effective January 1, 2005.
- "E'' to indicate items or services that are not covered by Medicare or codes that not recognized by Medicare.
- "F'' to indicate acquisition of corneal tissue, which is paid on a reasonable cost basis and certain CRNA services that are paid on a reasonable cost basis.
- "G'' to indicate drugs, biologicals, and radiopharmaceutical agents that are paid under the OPPS transitional pass-through rules.
- "H'' to indicate devices that are paid under the OPPS transitional pass-through rules and brachtheraphy sources that are paid on a cost basis.
- "K'' to indicate drugs, biologicals (including blood and blood products), and radiopharmaceutical agents that are paid in separate APCs under the OPPS, but that are not paid under the OPPS transitional pass-through rules.
- "L'' to indicate flu and pneumococcal immunizations that are paid at reasonable cost but to which no coinsurance or copayment apply.
- "N'' to indicate services that are paid under the OPPS, but for which payment is packaged into another service or APC group.
- "P'' to indicate services that are paid under the OPPS, but only in partial hospitalization programs.
- "S'' to indicate significant procedures that are paid under the OPPS, but to which the multiple procedure reduction does not apply.
- "T'' to indicate significant services that are paid under the OPPS and to which the multiple procedure payment discount under the OPPS applies.
- "V'' to indicate medical visits (including emergency department or clinic visits) that are paid under the OPPS.
- "X'' to indicate ancillary services that are paid under the OPPS.
- "Y'' to indicate nonimplantable durable medical equipment that must be billed directly to the durable medical equipment regional carrier rather than to the fiscal intermediary.

We are proposing the payment status indicators identified above for each HCPCS code and each APC in Addenda A and B and are requesting comments on the appropriateness of the indicators we have assigned.

2. Comment Indicators

In the November 1, 2002 and the November 7, 2003 final rules with comment period, which implemented changes in the OPPS for CYs 2003 and 2004, respectively, we provided code condition indicators in Addendum B. The code condition indicators and their meaning are as follows:

- "DG''—Deleted code with a grace period; Payment will be made under the deleted code during the 90-day grace period.
- "DNG''—Deleted code with no grace period; Payment will not be made under the deleted code.
- "NF''—New code final APC assignment; Comments were accepted on a proposed APC assignment in the Proposed Rule; APC assignment is no longer open to comment.
- "NI''—New code interim APC assignment; Comments will be accepted on the interim APC assignment for the new code.

Medicare has permitted a 90-day grace period after implementation of an updated medical code set, such as the HCPCS, to give providers time to incorporate new codes in their coding and billing systems and to remove the discontinued codes. HCPCS codes are updated annually every January 1, so the grace period for billing discontinued HCPCS was implemented every January 1 through March 31.

The Health Insurance Portability and Accountability Act (HIPAA) transaction and code set rules require usage of the medical code set that is valid at the time that the service is provided. Therefore, effective January 1, 2005, CMS is eliminating the 90-day grace period for billing discontinued HCPCS codes. Details about elimination of the 90-day grace period for billing discontinued HCPCS codes were issued to our contractors on February 6, 2004, in Transmittal 89, Change Request 3093.

In order to be consistent with the HIPPA rule that results in the elimination of the 90-day grace period for billing discontinued HCPCS codes, we are proposing, effective January 1, 2005, to delete code condition indicators "DNG'' and "DG''. We are proposing to designate codes that are

discontinued effective January 1, 2005 with status indicator ''D,'' as described in section VII.C.1. of this preamble.

Further, we are proposing to rename ''code condition'' indicators as ''comment indicators.'' In Addendum D2 to this proposed rule, we list the following two comment indicators that we are proposing to use to identify HCPCS codes assigned to APCs that are or are not subject to comment:

- ''NF''—New code, final APC assignment; Comments were accepted on a proposed APC assignment in the Proposed Rule; APC assignment is no longer open to comment.
- ''NI''—New code, interim APC assignment; Comments will be accepted on the interim APC assignment for the new code.

D. Observation Services

[If you choose to comment on issues in this section, include the caption ''Observation Services'' at the beginning of your comment.]

Frequently, beneficiaries are placed in ''observation status'' in order to receive treatment or to be monitored before making a decision concerning their next placement (that is, admit to the hospital or discharge). This status assignment occurs most frequently after surgery or a visit to the emergency department. For a detailed discussion of the clinical and payment history of observation services, see the November 1, 2002 final rule with comment period (67 FR 66794).

Before the implementation of the OPPS in CY 2000, payment for observation care was made on a reasonable cost basis, which gave hospitals a financial incentive to keep beneficiaries in ''observation status'' even though clinically they were being treated as inpatients. With the initiation of the OPPS, observation services were no longer paid separately; that is, they were not assigned to a separate APC. Instead, costs for observation services were packaged into payments for the services with which the observation care was associated.

Beginning in early 2001, the APC Panel began discussing the topic of separate payment for observation services. In its deliberations, the APC Panel asserted that observation services following clinical and emergency room visits should be paid separately, and that observation following surgery should be packaged into the payment for the surgical procedure. For CY 2002, we implemented separate payment for observation services (APC 0339) under the OPPS for three medical conditions: chest pain, congestive heart failure, and asthma. A number of accompanying requirements were established, including the billing of an evaluation and management visit in conjunction with the presence of certain specified diagnosis codes on the claim, hourly billing of observation care for a minimum of 8 hours up to a maximum of 48 hours, timing of observation beginning with the clock time on the nurse's admission note and ending at the clock time on the physician's discharge orders, a medical record documenting that the beneficiary was under the care of a physician who specifically assessed patient risk to determine that the beneficiary would benefit from observation care, and provision of specific diagnostic tests to beneficiaries based on their diagnoses. In developing this policy for separately payable observation services, we balanced issues of access, medical necessity, potential for abuse, and the need to ensure appropriate payment. We selected the three medical conditions, noted previously, and the accompanying diagnosis codes and diagnostic tests to avoid significant morbidity and mortality from inappropriate discharge while, at the same time, avoiding unnecessary inpatient admissions.

Over the past 2 years, we have continued to review observation care claims data for information on utilization and costs, along with additional information provided to us by physicians and hospitals concerning our current policies regarding separately payable observation services. Our primary goal is to ensure that Medicare beneficiaries have access to medically necessary observation care. We also want to ensure that separate payment is made only for beneficiaries actually receiving clinically appropriate observation care.

In January 2003, the APC Panel established an Observation Subcommittee. Over the last year, this subcommittee has held discussions concerning observation care and reviewed data extracted from claims that reported observation services. The subcommittee presented the results of its deliberations to the full APC Panel at the February 2004 meeting. The APC Panel recommendations regarding observation care provided under the OPPS were broad in scope and included elimination of the diagnosis requirement for separate payment for observation services, elimination of the requirement for the concomitant diagnostic tests for patients receiving observation care, unpackaging of observation services beyond the typical expected recovery time from surgical and interventional procedures, and modification of the method for measuring beneficiaries' time in observation to make it more compatible with routine hospital practices and their associated electronic systems.

In response to the APC Panel recommendations, we undertook a number of studies regarding observation services, while acknowledging data limitations from the brief 2-year experience the OPPS has had with separately payable observation services.

To assess the appropriateness of our proposal not to pay separately for observation services following surgical or interventional procedures, we analyzed the claims for these procedures to determine the extent to which the claims reported packaged observation services codes. This analysis revealed that while observation services are being reported on some claims for surgical and interventional procedures, the great majority of claims for these procedures reported no observation services. The packaged status of these observation services codes may result in underreporting their frequency, but the proportion of surgical and interventional procedures reported with the packaged observation services codes was so small that any increase would not change our substantive conclusion. This confirms our belief that, although an occasional surgical case may require a longer recovery period than expected for the procedure, as a rule, surgical outpatients do not require observation care. Given the rapidly changing nature of outpatient surgical and interventional services, it would be difficult to determine an expected typical recovery time for each procedure. We have concerns about overutilization of observation services in the post-procedural setting as partial replacement for recovery room time. However, we note that, to the extent observation care or extended recovery services are provided to surgical or interventional patients, the cost of that care is packaged into the payment for the procedural APC which may result in higher median costs for those procedures.

We also analyzed the possibility of expanding the list of medical conditions for separately payable visit-related observation services, altering the requirements for diagnostic tests while in observation, and modifying the rules for counting time in observation care.

We looked at CY 2003 OPPS claims data for all packaged visit-related observation care for all medical conditions in order to determine whether or not there were other diagnoses that would be candidates for separately payable observation services. Our analysis confirmed that the three

diagnoses that are currently eligible for separate payment for observation services are appropriate, as those diagnoses are frequently reported in our visit-related claims with packaged observation services. In fact, diagnoses related to chest pain were, by far, the diagnosis most frequently reported for observation care, either separately payable or packaged. Other diagnoses that appeared in the claims data with packaged observation services included syncope and collapse, transient cerebral ischemia, and hypovolemia.

The packaged status of those observation stays means that the data are often incomplete and the frequency of services may be underreported. Generally, information about packaged services is not as reliably reported as is that for separately paid services. However, we are not convinced that, for those other conditions (such as hypovolemia, syncope and collapse, among others), there is a well-defined set of hospital services that are distinct from the services provided during a clinic or emergency room visit. Separately payable observation care must include specific, clinically appropriate services, and we are still accumulating data and experience for the three medical conditions for which we are currently making separate payment. Therefore, we believe it is premature to expand the conditions for which we would separately pay for visit-related observation services.

Hospitals have indicated that, even in the cases where the diagnostic tests have been performed, to assure that billing requirements for separately payable observation services under APC 0339 are met, they must manually review the medical records to prepare the claims. If they do not conduct this manual review, they may not be coding appropriately for separately payable observation services.

We have also received comments from the community and the APC Panel asserting that the requirements for diagnostic testing are overly prescriptive and administratively burdensome, and that hospitals may perform tests to comply with the CMS requirements, rather than based on clinical need. For example, a patient admitted directly to observation care with a diagnosis of chest pain may have had an electrocardiogram in a physician's office just prior to admission to observation and may only need one additional electrocardiogram while receiving observation care. Thus, two more electrocardiograms performed in the hospital as required under the current OPPS observation policy might not be medically necessary.

We continue to believe that the diagnostic testing criteria we established for the three medical conditions are the minimally appropriate tests for patients receiving a well-defined set of hospital observation services for those conditions. The previous example, notwithstanding, we also continue to believe that the majority of these tests would be performed in the hospital outpatient setting. We define observation care as an active treatment to determine if a patient's condition is going to require that he or she be admitted as an inpatient or if the condition resolves itself and the patient is discharged. The currently required diagnostic tests reflect that an active assessment of the patient was being undertaken, and we believe they are generally medically necessary to determine whether a beneficiary will benefit from being admitted to observation care and aid in determining the appropriate disposition of the patient following observation care.

After careful consideration, we agree that specifying which diagnostic tests must be performed as a prerequisite for payment of APC 0339 may be imposing an unreasonable reporting burden on hospitals and may, in some cases, result in unnecessary tests being performed. Therefore, beginning in CY 2005, we are proposing to remove the current requirements for specific diagnostic testing, and rely on clinical judgment in combination with internal and external quality review processes to ensure that appropriate diagnostic testing (which we expect would include some of the currently required diagnostic tests) is provided for patients receiving high quality, medically necessary observation care.

Accordingly, we are proposing that, beginning in CY 2005, the following tests would no longer be required to receive payment for APC 0339 (Observation):

- For congestive heart failure, a chest x-ray (71010, 71020, 71030), and electrocardiogram (93005) and pulse oximetry (94760, 94761, 94762)
- For asthma, a breathing capacity test (94010) or pulse oximetry (94760, 94761, 94762)
- For chest pain, two sets of cardiac enzyme tests; either two CPK (82550, 82552, 82553) or two troponins (84484, 84512) and two sequential electrocardiograms (93005)

We believe that this proposed policy change would benefit hospitals because it would reduce administrative burden, allow more flexibility in management of beneficiaries in observation care, provide payment for clinically appropriate care, and remove a requirement that may have resulted in duplicative diagnostic testing.

Hospitals and the APC Panel further suggested that we modify the method for accounting for the beneficiary's time in observation care. Currently, hospitals report the time in observation beginning with the admission of the beneficiary to observation and ending with the physician's order to discharge the patient from observation. There are two problems related to using the time of the physician discharge order to determine the ending time of observation care. First, providers assert that it is not possible to electronically capture the time of the physician's orders for discharge. As a result, manual medical record review is required in order to bill accurately. Second, the hospital may continue to provide specific discharge-related observation care for a short time after the discharge orders are written and, therefore, may not be allowed to account for the full length of the observation care episode. In an effort to reduce hospitals' administrative burden related to accurate billing, we are proposing to modify our instructions for counting time in observation care to end at the time the outpatient is actually discharged from the hospital or admitted as an inpatient. Our expectation is that specific, medically necessary observation services are being provided to the patient up until the time of discharge. However, we do not expect reported observation time to include the time patients remain in the observation area after treatment is finished for reasons that include waiting for transportation home.

Although beneficiaries may be in observation care up to 48 hours or longer, we believe that, in general, 24 hours is adequate for the clinical staff to determine what further care the patient needs. In CY 2005, we would continue to make separate payment for observation care based on claims meeting the requirement for payment of HCPCS code G0244 (Observation care provided by a facility to a patient with CHF, chest pain, or asthma, minimum 8 hours, maximum 48 hours). However, we are proposing not to include claims reporting more than 48 hours of observation care in calculating the final payment rate for APC 0339.

In CY 2005, we expect OPPS payments for observation care to increase over CY 2004 levels for two reasons. First, our proposal to eliminate the requirement that specific diagnostic tests be performed in order to receive separate payment for observation care will result in more observation stays being paid for under APC 0339. We identified a number of CY 2003 claims

with packaged observation services reported for congestive heart failure (CHF), asthma, and chest pains that would have qualified for separate payment absent the requirement that certain diagnostic tests be reported on the same claim. In the CY 2003 claims data we used for our analyses, we identified about 55,000 claims coded with G0244 for separate payment in APC 0339. We also identified approximately 13,500 claims coded for observation care provided to beneficiaries with one of the three eligible medical conditions that did not report HCPCS code G0244 for separate payment. Our analysis revealed that those claims satisfy all of the criteria for separate payment of observation services if we remove the requirements for diagnostic tests. As mentioned above, hospitals report that billing for separately payable observation services requires manual medical record review and the separate payment may not offset the cost of the additional work even if patients' observation stays meet our criteria for separately payable observation services. Therefore, if we adopt our proposed changes, we expect the volume of claims for payment under APC 0339 to increase in CY 2005.

This volume increase, combined with the slightly higher median cost calculated for APC 0339 based on CY 2003 claims, would likely result in higher aggregate Medicare payments to hospitals for observation care in CY 2005 than in previous years. We attribute the increase in payment rate for APC 0339 to an increase in the relative level of charges reported by hospitals for observation services in CY 2003, compared to the relative level of charges reported by hospitals for all other outpatient services furnished during the same period. Our budget neutrality simulations, which we discuss in section XVI. of this preamble take into account both the increased payment for APC 0339 proposed for CY 2005, as well as the increase in the volume of separately payable observation services that we project could result from the changes in criteria that we are proposing for CY 2005.

Moreover, the increase in payments for observation care may be offset by a modest decrease in the number of previously required diagnostic tests performed by hospitals for patients in observation and in the reduction of billing for HCPCS code G0264, which pays for the initial nursing assessment of a patient directly admitted to observation for congestive heart failure, asthma, or chest pain when the stay does not meet all of the criteria for G0244.

In summary, to receive separate payment for medically necessary observation services, G0244 in APC 0339, involving specific goals and a plan of care that are distinct from the goals and plan of care for an emergency department, physician office, or clinic visit, we are proposing the following requirements beginning in CY 2005:

- The beneficiary must have one of three medical conditions: congestive heart failure, chest pain, or asthma. The hospital bill must report as the admitting or principal diagnosis an appropriate ICD–9–CM code to reflect the condition. The eligible ICD–9–CM diagnosis codes for CY 2005 are shown in Table 34 below.
- The hospital must provide and report on the bill an emergency department visit (APC 0610, 0611, or 0612), clinic visit (APC 0600, 0601, or 0602), or critical care (APC 0620) on the same day or the day before the separately payable observation care (G0244) is provided. For direct admissions to observation, in lieu of an emergency department visit, clinic visit, or critical care, G0263 (Adm with CHF, CP, asthma) must be billed on the same day as G0244.
- HCPCS code G0244 must be billed for a minimum of 8 hours.
- No procedures with a T status indicator, except the code for infusion therapy of other than a chemotherapy drug (currently HCPCS code Q0081 or as proposed in this proposed rule, CPT code 90780), can be reported on the same day or day before observation care is provided.
- Observation time must be documented in the medical record and begins with the beneficiary's admission to an observation bed and ends when he or she is discharged from the hospital.
- The beneficiary must be in the care of a physician during the period of observation, as documented in the medical record by admission, discharge, and other appropriate progress notes that are timed, written, and signed by the physician.
- The medical record must include documentation that the physician explicitly assessed patient risk to determine that the beneficiary would benefit from observation care.

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Table 34.--CY 2005 Eligible Diagnosis Codes For Billing Observation Services

Required Diagnosis For:	Eligible ICD-9-CM Code	Code Descriptor
Chest Pain	411.0	Postmyocardial infarction syndrome
	411.1	Intermediate coronary syndrome
	411.81	Coronary occlusion without myocardial infarction
	411.89	Other acute ischemic heart disease
	413.0	Angina decubitus
	413.1	Prinzmetal angina
	413.9	Other and unspecified angina pectoris
	786.05	Shortness of breath
	786.50	Chest pain, unspecified
	786.51	Precordial pain
	786.52	Painful respiration
	786.59	Other chest pain
Asthma	493.01	Extrinsic asthma with status asthmaticus
	493.02	Extrinsic asthma with acute exacerbation
	493.11	Intrinsic asthma with status asthmaticus
	493.12	Intrinsic asthma with acute exacerbation
	493.21	Chronic obstructive asthma with status asthmaticus
	493.22	Chronic obstructive asthma with acute exacerbation
	493.91	Asthma, unspecified with status asthmaticus
	493.92	Asthma, unspecified with acute exacerbation
Heart Failure	391.8	Other acute rheumatic heart disease
	398.91	Rheumatic heart failure (congestive)
	402.01	Malignant hypertensive heart disease with congestive heart failure
	402.11	Benign hypertensive heart disease with congestive heart failure
	402.91	Unspecified hypertensive heart disease with congestive heart failure
	404.01	Malignant hypertensive heart and renal disease with congestive heart failure
	404.03	Malignant hypertensive heart and renal disease with congestive heart and renal failure
	404.11	Benign hypertensive heart and renal disease with congestive heart failure
	404.13	Benign hypertensive heart and renal disease with congestive heart and renal failure

Required Diagnosis For:	Eligible ICD-9-CM Code	Code Descriptor
	404.91	Unspecified hypertensive heart and renal disease with congestive heart failure
	404.93	Unspecified hypertensive heart and renal disease with congestive heart and renal failure
	428.0	Congestive heart failure
	428.1	Left heart failure
	428.20	Unspecified systolic heart failure
	428.21	Acute systolic heart failure
	428.22	Chronic systolic heart failure
	428.23	Acute on chronic systolic heart failure
	428.30	Unspecified diastolic heart failure
	428.31	Acute diastolic heart failure
	428.32	Chronic diastolic heart failure
	428.33	Acute on chronic diastolic heart failure
	428.40	Unspecified combined systolic and diastolic heart failure
	428.41	Acute combined systolic and diastolic heart failure
	428.42	Chronic combined systolic and diastolic heart failure
	428.43	Acute on chronic combined systolic and diastolic heart failure
	428.9	Heart failure, unspecified

E. Procedures That Will Be Paid Only as Inpatient Procedures

[If you choose to comment on issues in this section, include the caption ''Inpatient Procedures'' at the beginning of your comment.]

Before implementation of the OPPS, Medicare paid reasonable costs for services provided in the outpatient department. 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.

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. In the April 7, 2000 final rule with comment period, we identified procedures that are typically provided only in an inpatient setting and, therefore, would not be paid by Medicare under the OPPS (65 FR 18455). 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. These are services that require inpatient care because of the nature of the procedure, the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, or the underlying physical condition of the patient. As we discussed in the April 7, 2000 final rule with comment period (65 FR 18455) and the November 30, 2001 final rule (66 FR 59856), we use 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 (67 FR 66792), 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 multiple 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 proposed by us for addition to the ASC list.

At the February 2004 meeting, the APC Panel made the recommendation to remove the following four abscess drainage CPT codes from the inpatient list: 44901, 49021, 49041, and 49061. As discussed in section II.G. of this preamble, we agree with the APC Panel's recommendation and we are proposing to remove these four abscess codes from the inpatient list and to assign them to APC 0037 for OPPS payment in CY 2005.

The APC Panel also made a recommendation to either eliminate the inpatient list from the OPPS or to evaluate the current list of procedures for any other appropriate changes. To determine the codes to be removed from the inpatient list, we have evaluated those codes that are performed in all sites of service other than the hospital inpatient setting approximately 60 percent or more of the time. We have chosen 60 percent as a threshold because, in general, we believe that a procedure should be considered for removal from the inpatient list if there is evidence that it is being performed less than one half of the time in the hospital inpatient setting. For procedures where data have shown that they can be done in a safe and appropriate manner on an outpatient basis in a variety of different hospitals, we believe that it would be reasonable to consider the removal of the procedure from the inpatient list. After careful evaluation of the list of inpatient codes against our criteria, we are proposing to remove the procedures listed in Table 35 from the inpatient list and to place them in APCs for payment under the OPPS. All of these codes would be assigned a status indicator ''T'', except for CPT codes 00174 and 00928, which would be assigned a status indicator ''N'' because, under the OPPS, anesthesia codes are packaged into the procedures with which they are billed.

Table 35.-- Proposed Procedure Codes to Be Removed From Inpatient List and Proposed APC Assignment

HCPCS	Description	Proposed APC	SI
00174	Anesth, pharyngeal surgery	n/a	N
00928	Anesth, removal of testis	n/a	N
21356	Treat cheek bone fracture	0254	T
21557	Remove tumor, neck/chest	0022	T
22222	Revision of thorax spine	0208	T
24149	Radical resection of elbow	0050	T
31292	Nasal/sinus endoscopy, surg	0075	T
43510	Surgical opening of stomach	0141	T
45541	Correct rectal prolapse	0150	T
50020	Renal abscess, open drain	0162	T
50570	Kidney endoscopy	0160	T
50572	Kidney endoscopy	0160	T
50574	Kidney endoscopy & biopsy	0160	T
50575	Kidney endoscopy	0163	T
50576	Kidney endoscopy & treatment	0161	T
53085	Drainage of urinary leakage	0166	T
58770	Create new tubal opening	0195	T
50578	Renal endoscopy/radiotracer	0161	T
44901	Drain app abscess, precut	0037	T
49021	Drain abdominal abscess	0037	T
49041	Drain, percut, abdom abscess	0037	T
49061	Drain, percut, retroper absc	0037	T

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For the reasons stated above, we are not proposing to accept the APC Panel's recommendation to completely eliminate the inpatient list for CY 2005. However, we are soliciting comments, especially from professional societies and hospitals, on whether these procedures are appropriate for removal from the inpatient list and on whether any other such procedures should be paid under the OPPS. We are also asking commenters who recommend that a procedure that is currently on the inpatient list be reclassified to an APC to include evidence (preferably from peer-reviewed medical literature) that the procedure is being performed on an outpatient basis in a safe and effective manner. We request that commenters suggest an appropriate APC assignment for the procedure, and furnish supporting data, in the event that we determine in the final rule, based on comments, that the procedure would be payable under the OPPS in CY 2005.

F. Hospital Coding for Evaluation and Management Services

[If you choose to comment on issues in this section, include the caption "E/M Services Guidelines'' at the beginning of your comment.]

1. Background

Currently, for claims processing purposes, we direct hospitals to use the CPT codes used by physicians to report clinic and emergency department visits on claims paid under the OPPS. However, we have received comments suggesting that the CPT codes are insufficient to describe the range and mix of services provided to patients in the clinic and emergency department setting because they are defined to reflect only the activities of physicians (for example, ongoing nursing care, and patient preparation for diagnostic tests). For both clinic and emergency department visits, there are currently five levels of care. To facilitate proper coding, we require each hospital to create an internal set of guidelines to determine what level of visit to report for each patient (April 7, 2000, final rule with comment period (65 FR 18434)).

We have continued our efforts to address the situation of proper coding of clinic and emergency department visits to ensure proper Medicare payments to hospitals. Commenters who responded to the August 24, 2001 OPPS proposed rule (66 FR 44672) recommended that we retain the existing evaluation and management coding system until facility-specific evaluation and management codes for emergency department and clinic visits, along with national coding guidelines, were established. Commenters also recommended that we convene a panel of experts to develop codes and guidelines that are simple to understand and to implement, and that are compliant with the HIPAA requirements. We agreed with these commenters, and in our November 1, 2002 OPPS final rule (67 FR 66792), we

stated that we believed the most appropriate forum for development of new code definitions and guidelines would be an independent expert panel that could provide information and data to us. We believed that, in light of the expertise of organizations such as the AHA and the AHIMA, these organizations were particularly well equipped to do so and to provide ongoing education to providers.

The AHA and the AHIMA, on their own initiative, convened an independent expert panel comprised of members of the AHA and AHIMA, as well as representatives of the American College of Emergency Physicians, the Emergency Nurses Association, and the American Organization of Nurse Executives, to develop code descriptions and guidelines for hospital emergency department and clinic visits and to provide us with the information and data. In June 2003, we received the panel's input concerning a set of national coding guidelines for emergency and clinic visits.

We are currently considering the panel's set of coding guidelines and the public comments we have received in response to them. In the November 7, 2003 OPPS final rule with comment period (68 FR 63463), we also indicated that we would implement new evaluation and management codes only when we are also ready to implement guidelines for their use. We further indicated that we would allow ample opportunity for public comment, systems changes, and provider education before implementing such new coding requirements.

2. Proposal for Evaluation and Management Guidelines

In the November 7, 2003 OPPS final rule with comment period (68 FR 63463), we discussed our primary concerns and direction for developing the proposed coding guidelines for emergency department and clinic visits and indicated our plans to make available for public comment the proposed coding guidelines that we are considering through the CMS OPPS website as soon as we have completed them. We will notify the public through our "listserve'' when the proposed guidelines will become available. To subscribe to this listserve, individuals should access the following website: *http://www.cms.hhs.gov/medlearn/listserv.asp* and follow the directions to the OPPS listserve. When we post the proposed guidelines on the website, we will provide ample opportunity for the public to comment.

In addition, we will provide ample time to train clinicians and coders on the use of new codes and guidelines and for hospitals to modify their systems. We anticipate providing at least 6 to 12 months notice prior to implementation of the new evaluation and management codes and guidelines. We will continue working to develop and test the new codes even though we have not yet made plans for their implementation.

G. Brachytherapy Payment Issues

[If you choose to comment on issues in this section, include the caption "Brachytherapy'' at the beginning of your comment.]

Payment for Brachytherapy Sources (Section 621(b) of Pub. L. 108–173, MMA)

Sections 621(b)(1) and (b)(2) of Pub. L. 108–173 amended the Act by adding section 1833(t)(16)(C) and section 1833(t)(2)(H), respectively, to establish separate 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. Charges for the brachytherapy devices may not be used in determining any outlier payments under the OPPS. In addition, consistent with our practice under the OPPS to exclude items paid at cost from budget neutrality consideration, these items must be excluded from budget neutrality as well. The period of payment under this provision is for brachytherapy sources furnished from January 1, 2004 through December 31, 2006.

In the OPPS interim final rule with comment period published on January 6, 2004 (69 FR 827), we implemented sections 621(b)(1) and 621(b)(2)(C) of Pub. L. 108–173. We stated that we will pay for the brachytherapy sources listed in Table 4 of the interim final rule with comment period (69 FR 828) on a cost basis, as required by the statute. The status indicator for brachytherapy sources was changed to "H.'' The definition of status indicator "H'' was for pass-through payment only for devices, but the brachytherapy sources affected by new sections 1833(t)(16)(C) and 1833(t)(2)(H) of the Act are not pass-through device categories. Therefore, we also changed, for CY 2004, the definition of payment status indicator "H'' to include nonpass-through brachytherapy sources paid on a cost basis. This use of status indicator "H'' is a pragmatic decision that allows us to pay for brachytherapy sources in accordance with new section 1833(t)(16)(C) of the Act, effective January 1, 2004, without having to modify our claims processing systems. We stated in the January 6, 2004 interim final rule with comment period that we would revisit the use and definition of status indicator "H'' for this purpose in the OPPS update for CY 2005. Therefore, in this proposed rule, we are soliciting further comments on this policy.

As we indicated in the January 6, 2004 interim final rule with comment period, we began payment for the brachytherapy source in HCPCS code C1717 (Brachytx source, HCR lr–192) based on the hospital's charge adjusted to cost beginning January 1, 2004. Prior to enactment of Pub. L. 108–173, these sources were paid as packaged services in APC 0313. As a result of the requirement under Pub. L. 108–173 to pay for C1717 separately, we adjusted the payment rate for APC 0313, Brachtherapy, to reflect the unpackaging of the brachytherapy source.

Section 1833(t)(2)(H) of the Act, as added by section 621(b)(2)(C) of Pub. L. 108–173, 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 be created in a manner that reflects the number, isotope, and radioactive intensity of the devices of brachytherapy furnished, including separate groups for Palladium-103 and Iodine-125 devices.

We invited the public to submit recommendations for new codes to describe brachytherapy sources in a manner that reflects the number, radioisotope, and radioactive intensity of the sources. We requested commenting parties to provide a detailed rationale to support recommended new codes. We stated that we would propose appropriate changes in codes for brachytherapy sources in the CY 2005 OPPS update.

At its meetings of February 18 through 20, 2004, the APC Panel heard from parties that recommended the addition of two new brachytherapy codes and HCPCS codes for high activity Iodine-125 and high activity Palladium-103. The APC Panel, in turn, recommended that CMS establish new HCPCS codes and new APCs, on a per source basis, for these two brachytherapy sources.

We have considered this recommendation and agree with the APC Panel. Therefore, we are proposing to establish the following two new brachytherapy source codes for CY 2005:

- Cxxx1 Brachytherapy source, high activity, Iodine-125, per source
- Cxxx2 Brachytherapy source, high activity, Palladium-103, per source

In addition, we believe the APC Panel's recommendation to establish new HCPCS codes that would distinguish high activity Iodine-125 from high activity Palladium-103 on a per source basis is an approach that should be implemented for other brachytherapy code descriptors, as well. Specifically, that recommendation would require that we include in the HCPCS code descriptor for such brachytherapy sources that the new high activity sources are paid "per source." Therefore, we are proposing to include "per source" in the HCPCS code descriptors for all those brachytherapy source descriptors for which units of payment are not already delineated.

Further, a new linear source Palladium-103 came to our attention in CY 2003 by means of an application for a new device category for pass-through payment. While we declined to create a new category for pass-through payment, we believe that this source falls under the provisions of Pub. L. 108–173 for separate cost-based payment as a brachytherapy source. Accordingly, we are proposing to add, for separate payment, the following code of linear source Palladium-103: Cxxx3 Brachytherapy linear source, Palladium-103, per 1 mm.

Table 36 provides a complete listing of the HCPCS codes, long descriptors, APC assignments and status indicators that we are proposing for brachytherapy sources paid under the OPPS in CY 2005.

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Table 36.—Current and Proposed Separately Payable Brachytherapy Sources

HCPCS	Long Descriptor	APC	APC title	NEW Status Indicator
C1716	Brachytherapy source, Gold 198, per source	1716	Brachytx source, Gold 198	H
C1717	Brachytherapy source, High Dose Rate iridium 192, per source	1717	Brachytx source, HDR Ir-192	H
C1718	Brachytherapy source, Iodine 125, per source	1718	Brachytx source, Iodine 125	H
C1719	Brachytherapy source, Non-High Dose Rate Iridium 192, per source	1719	Brachytx source, Non-HDR Ir-192	H
C1720	Brachytherapy source, Palladium 103, per source	1720	Brachytx source, Paladium 103	H
C2616	Brachytherapy source, Yttrium-90, per source	2616	Brachytx source, Yttrium-90	H
C2632*	Brachytherapy solution, Iodine125, per mCi	2632	Brachytx sol, I-125, per mCi	H
C2633	Brachytherapy source, Cesium-131, per source	2633	Brachytx source, Cesium-131	H
Cxxx1**	Brachytherapy source, High Activity, Iodine-125, per source	TBD	Brachytx source, HA, I-125	H
Cxxx2**	Brachytherapy source, High Activity, Paladium-103, per source	TBD	Brachytx source, HA, P-103	H
Cxxx3**	Brachytherapy linear source, Paladium-103, per 1MM	TBD	Brachytx linear source, P-103	H

*Currently paid as a pass-through device category, scheduled to expire from pass-through payment as of January 1, 2005.
** Newly proposed brachytherapy payment codes beginning January 1, 2005.

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H. Payment for APC 0375, Ancillary Outpatient Services When Patient Expires

In CY 2003, we implemented a new modifier –CA, Procedure payable only in the inpatient setting when performed emergently on an outpatient who dies before admission. The purpose of this modifier is to allow payment, under certain conditions, for outpatient services on a claim that have the same date of service as a HCPCS code with status indicator "C" that is billed with modifier –CA. When a procedure with status indicator "C" (inpatient services not payable under the OPPS) was billed with modifier –CA, we made payment of a fixed amount, under New Technology APC 0977.

In the November 7, 2003 final rule with comment period, we implemented APC 0375 to pay for services furnished in CY 2004 on the same date billed for a procedure code with modifier –CA, (68 FR 63467). We were concerned that

continuing to pay a fixed amount under a new technology APC for otherwise payable outpatient services furnished on the same date of service that a procedure with status indicator ''C'' is performed emergently on an outpatient would not result in appropriate payment for these services. That is, continuing to make payment under a new technology APC would not allow us to establish a relative payment weight for the services, subject to recalibration based on actual hospital costs.

We implemented a payment rate of $1,150 for APC 0375, which is the payment amount for the restructured New Technology—Level XIII, APC 1513, that replaced APC 0977, in CY 2004. We also stated that for the CY 2005 update of the OPPS, we would calculate a median cost and relative payment weight for APC 0375 using charge data from CY 2003 claims for line items with a HCPC code and status indicator ''V,'' ''S,'' ''T,'' ''X,'' ''N,'' ''K,'' ''G,'' and ''H,'' in addition to charges for revenue codes without a HCPCS code, that have the same date of service reported for a procedure billed with modifier –CA. We would then determine whether to set payment for APC 0375 based on our claims data or continue a fixed payment rate for these special services.

In accordance with this methodology, for CY 2005 we reviewed the services on the 18 claims that reported modifier –CA in CY 2003. We calculated a median cost for the aggregated payable services on the 18 claims reporting modifier –CA in the amount of $2,804.18. The mix of outpatient services that were reported appeared reasonable for a patient with an emergent condition requiring immediate medical intervention, and revealed a wide range of costs, which would also be expected. Therefore, we are proposing to set the payment rate for APC 0375 in accordance with the same methodology we have followed to set payment rates for the other procedural APCS in CY 2005, based on the relative payment weight calculated for APC 0375.

VIII. Proposed Conversion Factor Update for CY 2005

[If you choose to comment on issues in this section, please indicate the caption ''Conversion Factor'' at the beginning of your comment.]

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 2005, 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 forecast of the hospital market basket increase for FY 2005 published in the IPPS proposed rule on May 18, 2004, is 3.3 percent (69 FR 28374). To set the proposed OPPS conversion factor for CY 2005, we increased the CY 2004 conversion factor of $54.561, as specified in the November 7, 2003 final rule (68 FR 63459), by 3.3 percent.

In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the proposed conversion factor for CY 2004 to ensure that the revisions we are proposing to update by means of the wage index are made on a budget-neutral basis. We calculated a proposed budget neutrality factor of 1.001 for wage index changes by comparing total payments from our simulation model using the proposed FY 2005 IPPS wage index values to those payments using the current (FY 2004) IPPS wage index values. In addition, for CY 2005, allowed pass-through payments have decreased to 0.13 percent of total OPPS payments, down from 1.3 percent in CY 2004. The proposed conversion factor is also adjusted by the difference in estimated pass-through payments of 1.17 percent.

The proposed market basket increase update factor of 3.3 percent for CY 2005, the required wage index budget neutrality adjustment of approximately 1.001, and the 1.17 percent adjustment to the pass-through estimate result in a proposed conversion factor for CY 2005 of $57.098.

IX. Proposed Wage Index Changes for CY 2005

[If you choose to comment on issues in this section, please include the caption ''Wage Index'' at the beginning of your comment.]

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 and the copayment standardized amount attributable to labor and labor-related cost. This adjustment must be made in a budget neutral manner.

As discussed in section III.B., of this preamble, we are proposing to standardize 60 percent of estimated costs (labor-related costs) for geographic area wage variation using the IPPS wage indices that are calculated prior to adjustments for reclassification to remove the effects of differences in area wage levels in determining the OPPS payment rate and the copayment standardized amount. The proposed IPPS pre-reclassified urban and rural wage indices for FY 2005 are reprinted in Addenda L and M of this proposed rule.

In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually. In this proposed rule, we are proposing to use the proposed corrected FY 2005 hospital IPPS wage index for urban areas published in the **Federal Register** on June 25, 2004 (69 FR 35919) and the proposed FY 2005 hospital IPPS wage index for rural areas published in the **Federal Register** on May 18, 2004 (69 FR 28580) to determine the wage adjustments for the OPPS payment rate and the copayment standardized amount for CY 2005. We note that the proposed FY 2005 IPPS wage indices reflect a number of proposed changes as a result of the new OMB standards for defining geographic statistical areas, the proposed implementation of a occupational mix adjustment as part of the wage index, and new wage adjustments provided for under Pub. L. 108–173. The following is a brief summary of the proposed changes in the FY 2005 IPPS wage indices and any adjustments that we are proposing to apply to the OPPS for CY 2005. (We refer the reader to the May 18, 2004 IPPS proposed rule (69 FR 28248) for a fuller discussion of the proposed changes to the wage indices.)

A. The proposed use of the new Core Based Statistical Areas (CBSAs) issued by the Office of Management and Budget (OMB) as revised standards for designating geographical statistical areas based on the 2000 Census data, to define labor market areas for hospitals for purposes of the IPPS wage index. The OMB revised standards were published in the **Federal Register** on December 27, 2000 (65 FR 82235), and OMB announced the new CBSAs on June 6, 2003, through an OMB bulletin. In the FY 2005 hospital IPPS proposed rule, for wage index purposes, we proposed to treat hospitals designated as rural under the new CBSA classification system that were previously located in an MSA as if they were located in their old MSA, and further proposed to maintain that MSA designation for determining a wage index for the next 3 years. To be consistent, we are proposing to apply the same criterion to TEFRA hospitals paid under the OPPS but not under the IPPS and to maintain that MSA designation for determining a wage index for the next 3 years. This proposed policy would impact six TEFRA providers for purposes of OPPS payment.

B. The proposed incorporation of a blend of an occupational mix adjusted wage index into the unadjusted wage

index to reflect the effect of hospitals' employment choices of occupational categories to provide specific patient care.

C. The reclassifications of hospitals to geographic areas for purposes of the wage index that were approved under the one-time appeal process for hospitals authorized under section 508 of Pub. L. 108–173 (May 18, 2004 IPPS proposed rule (69 FR 28265 through 28266)).

D. The proposed implementation of an adjustment to the wage index to reflect the "out-migration'' of hospital employees who reside in one county but commute to work in a different county with a higher wage index, in accordance with section 505 of Pub. L. 108–173 (May 18, 2004 IPPS proposed rule (69 FR 28266 through 28269). Hospitals paid under the IPPS located in the qualifying section 505 "out-migration'' counties received a wage index increase. We are proposing to apply the same criterion to TEFRA hospitals paid under the OPPS but not paid under the IPPS. Therefore, TEFRA hospitals located in a qualifying section 505 county would also receive an increase to their wage index under OPPS. These additional hospitals are listed in Addendum K to this proposed rule with all IPPS hospitals receiving a wage index increase because they are located in a qualifying 505 county.

The following proposed FY 2005 IPPS wage indices that were published in the May 18, 2004 **Federal Register** (69 FR 28195) or corrected in the June 25, 2004 **Federal Register** (69 FR 35919) are reprinted as Addenda in this OPPS proposed rule: Addendum H—Wage Index for Urban Areas; Addendum I—Wage Index for Rural Areas; Addendum J—Wage Index for Hospitals That Are Reclassified; Addendum K—Wage Index Adjustment for Commuting Hospital Employees (Out-Migration) in Qualifying Counties; Addendum L—Pre-Reclassified Wage Index for Urban Areas; Addendum M—Pre-Reclassified Wage Index for Rural Areas; Addendum N—Hospital Reclassifications and Redesignations by Individual Hospital under Section 508 of Pub. L. 108–173. We are proposing to use these IPPS indices, as they are finalized by July 30, 2004, to adjust the payment rates and coinsurance amounts that we will publish in the OPPS final rule for CY 2005. Because the reclassification that results from implementation of section 508 of Pub. L. 108–173 is not subject to budget neutrality, we have not taken it into account in developing the OPPS budget neutrality estimates for CY 2005. However, the wage index increases that result from implementation of section 505 of Pub. L. 108–173 are subject to budget neutrality. Therefore, we have included the wage index changes associated with section 505 of Pub. L. 108–173 in calculating the OPPS budget neutrality estimates for CY 2005.

X. Determination of Proposed Payment Rates and Outlier Payments for CY 2005

A. Calculation of the Proposed National Unadjusted Medicare Payment

[If you choose to comment on issues in this section, please indicate the caption "Payment Rate for APCs'' at the beginning of your comment.]

The basic methodology for determining prospective payment rates for OPD services under the OPPS is set forth in existing regulations at §§ 419.31 and 419.32. The payment rate for services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section VIII. of this proposed rule, and the relative weight determined under section III. of this proposed rule. Therefore, the national unadjusted payment rate for APCs contained in Addendum A to this proposed rule and for payable HCPCS codes in Addendum B to this proposed rule (Addendum B is provided as a convenience for readers) was calculated by multiplying the proposed CY 2005 scaled weight for the APC by the proposed CY 2005 conversion factor.

However, to determine the payment that would be made under the OPPS to a specific hospital for an APC for a service other than a drug, in a circumstance in which the multiple procedure discount does not apply, we take the following steps:

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

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. Addenda H, I, J, and L to this proposed rule, which reflect the new proposed geographic statistical areas as a result of revised OMB standards (urban and rural) to which hospitals would be assigned for FY 2005 under the IPPS and the reclassifications of hospitals under the one-time appeals process under section 508 of Pub. L. 108–173, contain the wage index values assigned to each area. The wage index values include the proposed occupational mix adjustment described in section IX. of this proposed rule that was developed for the IPPS.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county but who work in a different county with a higher wage index, in accordance with section 505 of Pub. L. 108–173. Addendum K contains the qualifying counties and the proposed wage index increase developed for the IPPS.

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.

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.

B. Proposed Hospital Outpatient Outlier Payments

[If you choose to comment on issues in this section, please indicate the caption "Outlier Payments'' at the beginning of your comment.]

For OPPS services furnished between August 1, 2000, and April 1, 2002, we calculated outlier payments in the aggregate for all OPPS services that appear on a bill in accordance with section 1833(t)(5)(D) of the Act. In the November 30, 2001 final rule (66 FR 59856 through 59888), we specified that, beginning with CY 2002, we calculate outlier payments based on each individual OPPS service. We revised the aggregate method that we had used to calculate outlier payments and began to determine outlier payments on a service-by-service basis.

As explained in the April 7, 2000 final rule with comment period (65 FR 18498), we set a target for outlier payments at 2.0 percent of total payments. For purposes of simulating payments to calculate outlier thresholds, we set the target for outlier payments at 2.0 percent for CYs 2001, 2002, 2003, and 2004. For reasons discussed in the November 7, 2003 final rule with comment period (68 FR 63469), for CY 2004, we established a separate outlier threshold for CMHCs. For CY 2004, the outlier threshold is met when costs of furnishing a service or procedure by a hospital exceed 2.6 times the APC payment amount or when

the cost of furnishing services by a CMHC exceeds 3.65 times the APC payment amount. The current outlier payment percentage is 50 percent of the amount of costs in excess of the threshold.

For CY 2005, we are proposing to continue to set the target for outlier payments at 2.0 percent of total OPPS payments (a portion of that 2.0 percent, 0.6 percent, would be allocated to CMHCs for partial hospitalization program (PHP) services).

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. They are not intended to pay hospitals additional amounts for specific services on a routine basis. In its March 2004 Report, MedPAC found that 50 percent of OPPS outlier payments in CY 2004 were for 21 fairly common services that had relatively low APC payment rates, such as plain film x-rays and pathology services. We are concerned by the MedPAC findings which indicate that a significant portion of outlier payments are being made for high volume, lower cost services rather than for unusually high cost services, contrary to the intent of an outlier policy. (A full discussion of the 2004 MedPAC recommendations related to the OPPS and the CMS response to those recommendations can be found in section XII. of this preamble.)

In light of the MedPAC findings, we are proposing to change the standard we have used to qualify a service for outlier payments since the OPPS was originally implemented. That is, in addition to the outlier threshold we have applied since the beginning of the OPPS, which requires that a hospital's cost for a service exceed the APC payment rate for that service by a specified multiple of the APC payment rate, we are proposing to add a fixed dollar threshold that would have to be met in order for a service to qualify for an outlier payment. Section 1833(t)(5)(A) of the Act gives the Secretary the authority to impose a fixed dollar threshold in addition to an APC multiplier threshold. By imposing a dollar threshold, we expect to redirect outlier payments from lower cost, relatively simple procedures to more complex, expensive procedures for which the costs associated with individual cases could be exceptionally high and for which hospitals have a financial risk would be at greater risk financially.

In this proposed rule, we are proposing to require that, in order to qualify for an outlier payment, the cost of a service must exceed 1.5 times the APC payment rate and the cost must also exceed the sum of the APC rate plus a $625 fixed dollar threshold. Based upon our review of the data, a threshold of $625 better meets our 2.0 percent targets. When the cost of a hospital outpatient service exceeds these thresholds, we would pay 50 percent of the amount by which the cost of furnishing the service exceeds 1.5 times the APC payment rate (the APC multiple) as an outlier payment.

We are proposing to set the dollar threshold at a level that would, for all intents and purposes, exclude outliers for a number of lower cost services. For example, under the CY 2004 methodology a service mapped to an APC with a payment rate of $20 would only have to exceed $52 (2.6 × APC payment amount) in order to qualify for an outlier payment. Our proposed policy for CY 2005 with the additional fixed dollar threshold would require that the service in this example exceed $645 in order to qualify for an outlier payment. That is, the cost of the service would have to exceed both 1.5 times the APC payment rate, or $30, and $645 ($20 + $625).

The proposed dollar threshold would also enable us to lower the APC multiplier portion of the total outlier threshold from 2.6 to 1.5. We have chosen a multiple of 1.5 because this continues to recognize some variability relative to APC payment implicit in the current statute, but limits its impact in determining outlier payments. Under the proposed changes to the outlier methodology, it would also be easier for the higher cost cases of a complex, expensive procedure or service to qualify for outlier payments because the $625 threshold is a small portion of the total payment rate for high cost services. For example, under the CY 2004 methodology, a service mapped to an APC with a payment rate of $20,000 would have to exceed $52,000 in order to qualify for an outlier payment but, as proposed for CY 2005, would have to exceed only $30,000. That is, the cost of the service would have to exceed both 1.5 times the APC payment rate, or $30,000, and $20,625 ($20,000 + $625). Further, outlier payments for unusually expensive cases would be higher because the APC multiplier for outlier payment would decrease from 2.6 to 1.5 times the APC payment rate.

As discussed in the following section pertaining to Proposed Payment for Partial Hospitalization services, we are proposing to set the APC multiplier outlier threshold for CMHCs for CY 2005 at 3.35 times the APC payment amount and the CY 2005 outlier payment percentage applicable to costs in excess of the threshold at 50 percent.

C. Proposed Payment for Partial Hospitalization

[If you choose to comment on issues in this section, please indicate the caption ''Partial Hospitalization'' at the beginning of your comment.]

1. 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. A partial hospitalization program (PHP) may be provided by a hospital to its outpatients or by a Medicare-certified CMHC. Section 1833(t)(1)(B)(i) of the Act provides the Secretary with the authority to designate the hospital outpatient services to be covered under the OPPS. Section 419.21(c) of the Medicare regulations that implement this provision specifies that payments under the OPPS will be made for partial hospitalization services furnished by CMHCs. Section 1883(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. Payment to providers under the OPPS for PHPs represents the provider's overhead costs associated with the program. 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. For a detailed discussion, *see* the April 7, 2000 OPPS final rule (65 FR 18452).

2. Proposed PHP APC Update for CY 2005

For calculation of the proposed CY 2005 per diem payment, we used the same methodology that was used to compute the CY 2004 per diem payment. For CY 2004, the per diem amount was based on three quarters of hospital and CMHC PHP claims data (for services furnished from April 1, 2002, through December 31, 2002). We used data from all hospital bills reporting condition code 41, which identifies the claim as partial hospitalization, and all bills from CMHCs because CMHCs are Medicare providers only for the purpose of providing partial hospitalization services. We used cost-to-charge ratios from the most recently available hospital and CMHC cost reports to

convert each provider's line item charges as reported on bills, to estimate the provider's cost for a day of PHP services. Per diem costs are then computed by summing the line item costs on each bill and dividing by the number of days on the bill.

Unlike hospitals, CMHCs do not file cost reports electronically and the cost report information is not included in the Healthcare Cost Report Information System (HCRIS). The CMHC cost reports are held by the Medicare fiscal intermediaries. In a Program Memorandum issued on January 17, 2003 (Transmittal A–03–004), we directed fiscal intermediaries to recalculate hospital and CMHC cost-to-charge ratios using the most recently settled cost reports by April 30, 2003. Following the initial update of cost-to-charge ratios, fiscal intermediaries were further instructed to continue to update a provider's cost-to-charge ratio and enter revised cost-to-charge ratios into the outpatient provider specific file. Therefore, for CMHCs, we use cost-to-charge ratios from the outpatient provider specific file. For CY 2005, we analyzed 12 months of data for hospital and CMHC PHP claims for services furnished between January 1, 2003, and December 31, 2003. Updated cost-to-charge ratios reduced the median cost per day for CMHCs. The revised medians are $313 for CMHCs and $213 for hospitals. Combining these files results in a median per diem PHP cost of $297. As with all APCs in the OPPS, the median cost for each APC is scaled to be relative to a mid-level office visit and the conversion factor is applied. We are proposing the resulting APC amount for PHP of $292.19 for CY 2005, of which $58.44 is the beneficiary's coinsurance.

3. 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. Further analysis indicated the use of outlier payments was contrary to the intent of the outlier policy as discussed previously in section X.B. above. Therefore, for CY 2004, we established a separate outlier threshold for CMHCs. 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 CY 2004, excluding outlier payments.

As stated in the November 7, 2003 final rule with comment period, CMHCs were projected to receive 0.5 percent of the estimated total OPPS payments in CY 2004. The CY 2004 outlier threshold is met when the cost of furnishing services by a CMHC exceeds 3.65 times the APC payment amount. The current outlier payment percentage is 50 percent of the amount of costs in excess of the threshold.

CMS and the Office of the Inspector General are continuing to monitor the excessive outlier payments to CMHCs. However, we do not yet have CY 2004 claims data that will show the effect of the separate outlier threshold for CMHCs that was effective January 1, 2004. Therefore, for CY 2005, as discussed in section X.B. of this preamble, we are proposing to continue to set the target for hospital outpatient outlier payments at 2.0 percent of total OPPS payments. We are proposing that a portion of that 2.0 percent, 0.6 percent, would be allocated to CMHCs for PHP services. We propose 0.6 percent for CMHCs because the percentage of CMHC's payment to total OPPS payment rose slightly in the CY 2003 claims data. In the absence of CY 2004 claims data, we developed simulations for CY 2005. As discussed in section X.B. of this preamble, we are proposing a dollar threshold in addition to an APC multiplier threshold for hospital OPPS outlier payments. However, because PHP is the only APC for which CMHCs may receive payment under the OPPS, we would not expect to redirect outlier payments by imposing a dollar threshold. Therefore, we are not proposing a dollar threshold for CMHC outliers. We are proposing to set the outlier threshold for CMHCs for CY 2005 at 3.35 percent times the APC payment amount and the CY 2005 outlier payment percentage applicable to costs in excess of the threshold at 50 percent.

XI. Proposed Beneficiary Copayments for CY 2005

[If you choose to comment on issues in this section, please indicate the caption "Copayment'' at the beginning of your comment.]

A. 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 specified percentages. For all services paid under the OPPS in CY 2005, the specified percentage is 45 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 coinsurance amount cannot be less than 20 percent of the OPD fee schedule amount.

B. Proposed Copayment for CY 2005

For CY 2005, we determined copayment amounts for new and revised APCs using the same methodology that we implemented for CY 2004 (see the November 7, 2003 final rule 68 FR 63458). The unadjusted copayment amounts for services payable under the OPPS effective January 1, 2005 are shown in Addendum A and Addendum B.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) in its March 2004 Report to the Congress: "Medicare Payment Policy,'' made two recommendations relating to the OPPS. This section provides responses to those recommendations.

Recommendation 3A–2: The Congress should increase payment rates for the OPPS by the projected rate of increase in the hospital market basket index for CY 2005.

Response: Section 1833(t)(3)(C)(ii) of the Act requires the Secretary 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 2005, the update is equal to the hospital inpatient market basket percentage applicable under section 1886(b)(3) of the Act to hospital discharges. The forecast of the hospital market basket increase for FY 2005 published in the IPPS proposed rule on May 18, 2004, is 3.3 percent (69 FR 63459). Therefore, in accordance with this statutory requirement, we are proposing to update the OPPS conversation factor for CY 2005 by 3.3 percent as discussed in section VIII. of this preamble.

Recommendation 3A–3: The Congress should eliminate the outlier policy under the outpatient PPS.

Response: We have carefully reviewed the MedPAC report regarding this recommendation and are concerned by

its findings which indicate that a significant portion of outlier payments are being made for high volume, lower cost services rather than for unusually high cost services, contrary to the intent of an outlier policy. While it is evident that the OPPS outlier payments cannot be discontinued by us without a legislative change by Congress, we believe that the MedPAC findings warrant a change in our standard for qualifying a hospital outpatient service for an outlier payment. Therefore, in light of the MedPAC findings we are proposing to change the standard we have used to qualify a service for an outlier payment since initial implementation of the OPPS. As discussed in section X.B. of this preamble, we are proposing to add a fixed dollar threshold requirement to the current threshold, which requires that a hospital's cost for a service exceed the APC payment rate for that service by a specified multiple in order to qualify for an outlier payment. That is, we are proposing to require, that in order to qualify for an outlier payment, the cost of a service must exceed 1.5 times the APC payment rate and the cost must also exceed the sum of the APC rate plus a $625 fixed dollar threshold. By imposing a dollar threshold in addition to an APC multiplier threshold, we expect to redirect outlier payments from lower cost and relatively simple procedures to more complex, expensive procedures for which the costs associated with individual cases could be exceptionally high.

We are not proposing to apply the fixed dollar threshold to CMHCs because partial hospitalization services are the only APC service for which CMHCs can receive payment under the OPPS, and we would not expect to redirect outlier payment by imposing a dollar threshold.

XIII. Addenda Files Available to the Public Via Internet

The data referenced for Addenda C and G to this proposed rule are available on the following CMS Web site via Internet only: *http://www.cms.hhs.gov/providers/hopps/*. We are not republishing the data represented in these two Addenda to this proposed rule because of their volume. For additional assistance, contact Chris Smith-Ritter at (410) 786–0378. Addendum C—Healthcare Common Procedure Coding System (HCPCS) Codes by Ambulatory Payment Classification (APC.)

This file contains the HCPCS codes sorted by the APCs into which they are assigned for payment under the OPPS. The file also includes the APC status indicators, relative weights, and OPPS payment amounts.

XIV. Collection of Information Requirements

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 evaluate fairly whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comments on each of these issues for the following information collection requirement:

Section 410.16 Initial preventive physical examination.

Proposed new section 410.16 would require, for the furnishing of education, counseling and referral services as part of an initial preventive physical examination, a written plan for obtaining the appropriate screening and other preventive services which are also covered as separate Medicare B Part services.

The burden associated with this requirement is the time required of the physician or practitioner to provide beneficiaries with education, counseling, and referral services and to develop and provide a written plan for obtaining screening and other preventive services.

While these requirements are subject to the PRA, the burden associated with these requirements is currently captured and discussed in the ''Revisions to Payment Policies Under the Physician Fee Schedule for CY 2005'' (CMS–1429–P). This section mirrors that proposed rule for convenience purposes.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: John Burke, CMS–1427–P, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, CMS Desk Officer

Comments submitted to OMB may also be e-mailed to the following address: e-mail: *Christopher_Martin@omb.eop.gov*, or faxed to OMB at (202) 395–6974.

XV. Response to Public Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments concerning the provisions of this proposed rule that we receive by the date and time specified in the **DATES** section of this preamble, and when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XVI. Regulatory Impact Analysis

A. OPPS: General

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 the effects of the provisions that would be implemented by this proposed rule would result in expenditures exceeding $100 million in any 1 year. We estimate the total increase (from changes in the proposed rule as well as enrollment, utilization,

and case mix changes) in expenditures under the OPPS for CY 2005 compared to CY 2004 to be approximately $1.5 billion. Therefore, this proposed rule is an economically significant rule under Executive Order 12866, and a major rule under 5 U.S.C. 804(2).

The RFA requires agencies to determine whether a rule would have a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year (*see* 65 FR 69432).

For purposes of the RFA, we have determined that approximately 37 percent of hospitals would be considered small entities according to the Small Business Administration (SBA) size standards. We do not have data available to calculate the percentages of entities in the pharmaceutical preparation manufacturing, biological products, or medical instrument industries that would be considered to be small entities according to the SBA size standards. For the pharmaceutical preparation manufacturing industry (NAICS 325412), the size standard is 750 or fewer employees and $67.6 billion in annual sales (1997 business census). For biological products (except diagnostic) (NAICS 325414), with $5.7 billion in annual sales, and medical instruments (NAICS 339112), with $18.5 billion in annual sales, the standard is 50 or fewer employees (see the standards website at *http://www.sba.gov/regulations/siccodes/*). Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we previously defined a small rural hospital as a hospital with fewer than 100 beds that is located outside of a Metropolitan Statistical Area (MSA) (or New England County Metropolitan Area (NECMA)). However, under the new labor market definitions that we are proposing to adopt, we no longer employ NECMAs to define urban areas in New England. Therefore, we now define a small rural hospital as a hospital with fewer than 100 beds that is located outside of an MSA. 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 NECMA. Thus, for purposes of the OPPS, we classify these hospitals as urban hospitals. We believe that the changes in this proposed rule would affect both a substantial number of rural hospitals as well as other classes of hospitals and that the effects on some may be significant. Therefore, we conclude that this proposed rule would have a significant impact on a substantial number of small entities.

Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This proposed rule would not mandate any requirements for State, local, or tribal governments. This proposed rule would not impose unfunded mandates on the private sector of more than $110 million dollars.

Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes 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 this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that it would not have an impact on the rights, roles, and responsibilities of State, local or tribal governments. The impact analysis (*see* Table 37) shows that payments to governmental hospitals (including State, local, and tribal governmental hospitals) would increase by 4.3 percent under the proposed rule.

B. Impact of Proposed Changes in This Proposed Rule

We are proposing 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 are also 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 proposed rule, we are proposing to update the conversion factor and the wage index adjustment for hospital outpatient services furnished beginning January 1, 2005 as we discuss in sections VIII. and IX., respectively, of this proposed rule. We are also proposing to revise the relative APC payment weights using claims data from January 1, 2003 through December 31, 2003. Finally, we are proposing to remove 6 devices and 12 drugs and biological agents from pass-through payment status. In particular, see section V.A.2 with regard to the expiration of pass-through status for devices and see section IV.A.2 with regard to the expiration of pass-through status for drugs and biological agents.

Under this proposed rule, the update change to the conversion factor as provided by statute as well as the additional money for the OPPS payments in CY 2005 as authorized by Pub. L. 108–173, including money for drugs and increases in the wage index adjustment, would increase total OPPS payments by 4.6 percent in CY 2005. The changes to the wage index and to the APC weights (which incorporate the cessation of pass-through payments for several drugs and devices) would not increase OPPS payments because the OPPS is budget neutral. However, the wage index and APC weight changes would change the distribution of payments within the budget neutral system as shown in Table 37 and described in more detail in this section.

C. Alternatives Considered

Alternatives to the changes we are making and the reasons that we have chosen the options we have are discussed throughout this proposed rule. Some of the major issues discussed in this proposed rule and options that affect our policies are discussed below.

Payment for Device-Dependent APCs

We package payment for an implantable device into the APC payment for the procedure performed to insert the device. Because almost all devices lost pass-through status at the end of CY 2002, we discontinued use of separate codes to report devices in CY 2003. We have found that claims that we use to set payment rates for device-dependent APCs frequently have packaged costs that are much lower than the cost of the device. This is attributed, in part, to variations in hospital billing practices. In response, we reestablished device codes for reporting on a voluntary basis in CY 2004.

The APC Panel recommended that we use CY 2004 device-dependent APC

rates updated for inflation as the CY 2005 payments. We considered this option but did not adopt it because it would not recognize changes in relative cost for these APCs and would not advance us towards our goal of using unadjusted claims data as the basis for payment weights for all OPPS services.

In addition to consideration of the APC Panel's recommendation, we considered using CY 2002 claims to calculate a ratio between the median calculated using all single bills and the median calculated using only claims with HCPCS codes for devices on them, and applying that ratio to the median calculated using CY 2003 claims data. We rejected this option because it assumes that the relationship between the costs of the claims with and without codes for devices is a valid relationship not only for CY 2002 but CY 2003 as well. It also assumes no changes in billing behavior. We have no reason to believe either of these assumptions is true and, therefore, we did not choose this option.

We do not believe that any of the above options would help us progress toward reliance on our data. Rather than adoption of any of those approaches, we developed an option to adjust the payment for only those device-dependent APCs that have the most dramatic decreases for CY 2005. We believe that the better payment approach for determining median costs for device-dependent APCs in CY 2005 would be to base these medians on the greater of (1) median costs calculated using CY 2003 claims data, or (2) 90 percent of the APC payment median used in CY 2004 for these services. We believe that this proposed adjustment methodology provides an appropriate transition to eventual use of all single bill claims data without adjustment.

We are also proposing to use "C'' codes to bill for the device-dependent procedures for which we adjusted the medians for CY 2005 as well as for a few APCs that require devices that are coming off pass-through payment in CY 2005 (a continuation of current billing practice). We believe that adoption of our proposal will mitigate barriers to beneficiary access to care while encouraging hospitals to bill correctly for the services they furnish. For a more detailed discussion of this issue, see section III. of the preamble.

Proposed Hospital Outpatient Outlier Payments

In its March 2004 Report, MedPAC made a recommendation to the Congress to eliminate the outlier provision under the OPPS. MedPAC made its recommendation after studying outlier payments on claims for services furnished during CY 2002 and concluding that in 2002, 50 percent of outlier payments were paid for 21 fairly common services that had relatively low APC payment rates, while high cost services accounted for only a small share of outlier payments. However, outlier payments are required under the statute; therefore, we cannot discontinue outlier payments absent a legislative change by the Congress.

In light of the MedPAC findings, we are proposing a change to the threshold we use for qualifying a service for outlier payments to add a fixed dollar threshold in addition to the threshold based on a multiple of the APC amount that we have applied since the beginning of the OPPS. For a more detailed discussion of this issue, see section X. of the preamble.

D. Limitations of Our Analysis

The distributional impacts represent the projected effects of the policy changes, as well as the statutory changes that would be effective for CY 2005 on various hospital groups. We estimate the effects of 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 are not proposing to make adjustments for future changes in variables such as service volume, service mix, or number of encounters. As we have done in previous proposed rules, we are soliciting comments and information about the anticipated effects of these proposed changes on hospitals and our methodology for estimating them.

E. Estimated Impacts of This Proposed Rule on Hospitals

The OPPS is a budget neutral payment system under which the increase to the total payments made under OPPS is limited by the increase to the conversion factor set under the methodology in the statute. The enactment of Pub. L. 108–173 on December 8, 2003, provided for the payment of additional dollars in 2005 to providers of OPPS services outside of the budget neutrality requirements for both specified covered outpatient drugs (see section V.A.3.a. of the preamble to this rule) and the wage indexes for specific hospitals through reclassification reform in section 508 of Pub. L. 108–173 (see section IX. of the preamble to this rule). Table 38 shows the estimated redistribution of hospital payments among providers as a result of a new APC structure and wage index, which are budget neutral; the estimated distribution of increased payments in CY 2005 resulting from the combined impact of APC recalibration and wage effects, and market basket update to the conversion factor; and estimated payments considering all proposed changes for CY 2005. In some cases, specific hospitals may receive more total payment in CY 2005 than in CY 2004 while in other cases they may receive less total payment than they received in CY 2004. However, our impact analysis suggests that no class of hospitals would receive less total payments in CY 2005 than in CY 2004. Because updates to the conversion factor, including the market basket and any reintroduction of pass-through dollars, are applied uniformly, the extent to which this proposed rule redistributes money would largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would change) and the impact of the wage index changes on the hospital.

Overall, the proposed OPPS rates for CY 2005 would have a positive effect for every category of hospital. Proposed changes will result in a 4.6 percent increase in Medicare payments, to all hospitals, exclusive of outlier and transitional pass-through payments. As described in the preamble, budget neutrality adjustments are made to the conversion factor and the relative weights to ensure that the revisions in the wage index, APC groups, and relative weights do not affect aggregate payments. The impact of the wage and APC recalibration changes are moderate across hospital groups.

To illustrate the impact of the proposed CY 2005 changes, our analysis begins with a baseline simulation model that uses the final CY 2004 weights, the FY 2004 final post-reclassification wage index without increases resulting from section 508 reclassifications, and the final CY 2004 conversion factor. Columns 2 and 3 in Table 38 reflect the independent effects of the changes in the APC reclassification and recalibration changes and the wage index, respectively. These effects are budget neutral, which is apparent in the overall zero impact in payment for all hospitals. Column 2 shows the independent effect of changes resulting from the reclassification of HCPCS codes among APC groups and the recalibration of APC weights based on a complete year of 2003 hospital OPPS claims data. We modeled the independent effect of APC recalibration by varying only the weights, final CY 2004 weights versus proposed CY 2005