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Department of Health and Human Services

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42 CFR Parts 410 and 419

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410 and 419

[CMS–1471–P]

RIN 0938–AL19

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 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. In addition, it would describe 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, 2004.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 6, 2003.

ADDRESSES: In commenting, please refer to file code CMS–1471–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail.

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–1471–P, P.O. Box 8018, Baltimore, MD 21244–8018.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses:

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

We encourage commenters submitting as comments information that contains beneficiary specific information (for example, medical records, or invoices with beneficiary identification) to remove any individually identifiable information, such as information that identifies an individual, diagnoses, addresses, telephone numbers, attending physician, medical record number, or Medicare or other insurance number. Moreover, individually identifiable beneficiary medical records, including progress notes, medical orders, test results, consultation reports, and photocopies of checks from hospitals or other documents that contain bank routing numbers should not be submitted to us. Persons or organizations submitting proprietary information as public comments must designate in writing if part or all of the information contained in such comments should be considered as exempt from disclosure under Exemption 4 of the Freedom of Information Act (FOIA). Generally, Exemption 4 of the FOIA protects trade secrets and commercial or financial information that is privileged or confidential, and affords the same protections as the Trade Secrets Act, which is also applicable. We will attempt to keep confidential and protect from disclosure information that qualifies under Exemption 4. However, only data that can be available for public inspection would be used for the final rule. For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Dana Burley, (410) 786–4532—outpatient prospective payment issues; Suzanne Asplen, (410) 786–4558 or Jana Petze, (410) 786–9374—partial hospitalization and community mental health centers issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call (410) 786–7197.

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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
ASC—Ambulatory surgical center
AWP—Average wholesale price
BBA—Balanced Budget Act of 1997
BIPA—Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
BBRA—Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999
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)
CPT—[Physicians'] Current Procedural Terminology, Fourth Edition, 2002, copyrighted by the American Medical Association
CY—Calendar year
DMEPOS—Durable medical equipment, prosthetics, orthotics, and supplies
DRG—Diagnosis-related group
DSH—Disproportionate Share Hospital
EACH—Essential Access Community Hospital
E/M—Evaluation and management
ESRD—End-stage renal disease
FACA—Federal Advisory Committee Act
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
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
MSA—Metropolitan statistical area
NECMA—New England County Metropolitan Area
OCE—Outpatient code editor
OMB—Office of Management and Budget
OPD—(Hospital) outpatient department
OPPS—(Hospital) outpatient prospective payment system
PHP—Partial hospitalization program
PM—Program memorandum
PPS—Prospective payment system
PPV—Pneumococcal pneumonia (virus)
PRA—Paperwork Reduction Act
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
TOPS—Transitional outpatient payments
USPDI—United States Pharmacopoeia Drug Information

I. Background

A. 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. The OPPS was first implemented for services furnished on or after August 1, 2000.

B. Summary of Rulemaking for the Outpatient Prospective Payment System

- On September 8, 1998, we published a proposed rule (63 FR 47552) to establish in regulations a PPS for hospital outpatient services, to eliminate the formula-driven overpayment for certain hospital outpatient services, and to extend reductions in payment for costs of hospital outpatient services. On June 30, 1999, we published a correction notice (64 FR 35258) to correct a number of technical and typographic errors in the September 1998 proposed rule including the proposed amounts and factors used to determine the payment rates.
- On April 7, 2000, we published a final rule with comment period (65 FR 18434) that addressed the provisions of the PPS for hospital outpatient services scheduled to be effective for services furnished on or after July 1, 2000. Under this system, Medicare payment for hospital outpatient services included in the PPS is made at a predetermined, specific rate. These outpatient services are classified according to a list of ambulatory payment classifications (APCs). The April 7, 2000 final rule with comment period also established requirements for provider departments and provider-based entities and prohibited Medicare payment for nonphysician services furnished to a hospital outpatient by a provider or supplier other than a hospital unless the services are furnished under arrangement. In addition, this rule extended reductions in payment for costs of hospital outpatient services as required by the BBA and amended by the BBRA. Medicare regulations governing the hospital OPPS are set forth at 42 CFR part 419.
- On June 30, 2000, we published a notice (65 FR 40535) announcing a delay in implementation of the OPPS from July 1, 2000 to August 1, 2000. We implemented the OPPS on August 1, 2000.
- On August 3, 2000, we published an interim final rule with comment period (65 FR 47670) that modified criteria that we use to determine which medical devices are eligible for transitional pass-through payments. The August 3, 2000 rule also corrected and clarified certain provider-based provisions included in the April 7, 2000 rule.
- On November 13, 2000, we published an interim final rule with comment period (65 FR 67798). This rule provided for the annual update to the amounts and factors for OPPS payment rates effective for services furnished on or after January 1, 2001. We implemented the 2001 OPPS on January 1, 2001. We also responded to public comments on those portions of the April 7, 2000 final rule that implemented related provisions of the BBRA and public comments on the August 3, 2000 rule.
- On November 2, 2001, we published a final rule (66 FR 55857) that announced the Medicare OPPS conversion factor for calendar year (CY) 2002. In addition, it described the Secretary's estimate of the total amount of the transitional pass-through payments for CY 2002 and the implementation of a uniform reduction in each of the pass-through payments for that year.
- On November 2, 2001, we also published an interim final rule with comment period (66 FR 55850) that set forth the criteria the Secretary will use to establish new categories of medical devices eligible for transitional pass-through payments under Medicare's OPPS.
- On November 30, 2001, we published a final rule (66 FR 59856) that revised the Medicare OPPS to implement applicable statutory requirements, including relevant provisions of BIPA, and changes resulting from continuing experience with this system. In addition, it described the CY 2002 payment rates for Medicare hospital outpatient services paid under the PPS. This final rule also announced a uniform reduction of 68.9 percent to be applied to each of the transitional pass-through payments for certain categories of medical devices and drugs and biologicals.
- On December 31, 2001, we published a final rule (66 FR 67494) that delayed, until no later than April 1, 2002, the effective date of CY 2002 payment rates and the uniform reduction of transitional pass-through payments that were announced in the November 30, 2001 final rule. In addition, this final rule indefinitely delayed certain related regulatory provisions.
- On March 1, 2002, we published a final rule (67 FR 9556) that corrected technical errors that affected the amounts and factors used to determine the payment rates for services paid under the Medicare OPPS and corrected the uniform reduction to be applied to transitional pass-through payments for CY 2002 as published in the November 30, 2001 final rule. These corrections and the regulatory provisions that had been delayed became effective on April 1, 2002.
- On November 1, 2002, we published a final rule (67 FR 66718) that revised the Medicare OPPS to update the payment weights and conversion factor for services payable under the 2003 OPPS on the basis of data from claims for services furnished from April 1, 2001 through March 31, 2002. The rule also removed from pass-through status most drugs and devices that had been paid under pass-through provisions in 2002 as required by the applicable provisions of law governing the duration of pass-through payment.

II. Proposed Changes to the Ambulatory Payment Classification (APC) Groups and Relative Weights

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 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. Section 1833(t)(9)(A) of the Act requires the Secretary, beginning in 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.''

For purposes of this proposed rule, we analyzed the APC groups within this statutory framework.

A. Recommendations of the Advisory Panel on APC Groups

1. Establishment of the Advisory Panel on APC Groups

Section 1833(t)(9)(A) of the Act requires that we consult with an outside panel of experts, the Advisory Panel on APC Groups (the Panel), to review the clinical integrity of the groups and weights. The Act specifies that the Panel will act in an advisory capacity. This expert panel, which is to be composed of representatives of providers subject to the OPPS (currently employed full-time, in their respective areas of expertise), reviews and advises us about the clinical integrity of the APC groups and their weights. The Panel is not restricted to using our data and may use data collected or developed by organizations outside the Department in conducting its review.

On November 21, 2000, the Secretary signed the charter establishing an ''Advisory Panel on APC Groups.'' The 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 renewed the charter. The new charter indicates that the Panel continues to be technical in nature, is governed by the provisions of the FACA, may convene ''up to three meetings per year,'' and is chaired by a Federal official.

To establish the 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 a colleague or themselves. After carefully reviewing the applications, we chose 15 highly qualified individuals to serve on the Panel.

Because of the loss of 6 Panel members in March 2003 due to the expiration of terms of office, retirement, and a career change, a **Federal Register** notice was published on February 28, 2003 (68 FR 9671), requesting nominations of Panel members. From the 40 nominations we received, 6 new members have been chosen and will be identified on the CMS Web site.

2. The Panel's Meetings

The first Panel meeting was held on February 27, February 28, and March 1, 2001. During the 2001 meeting, the Panel members felt that requiring consistency for all presentations with regard to format, data submission, and general information would assist them in analyzing the submissions and presentations and making recommendations. Therefore, upon the Panel's recommendation, the Research Subcommittee was established during the 2001 meeting.

The Panel began its 2002 meeting on January 22, 2002, by considering the Research Subcommittee's recommendation to the Panel on requirements for written submissions and oral presentations. The Research Subcommittee recommended that all future oral presentations and written submissions contain the following:

- Name, address, and telephone number of the proposed presenter.
- Financial relationship(s), if any, with any company whose products, services, or procedures are under consideration.
- CPT ([Physicians'] Current Procedural Technology) codes involved.
- APC(s) affected.
- Description of the issue.
- Clinical description of the service under discussion, with comparison to other services within the APC.
- Description of the resource inputs associated with the service under discussion, with a comparison to resource inputs for other services within the APC.
- Recommendations and rationale for change.
- Expected outcome of change and potential consequences of no change.

The Panel adopted these Subcommittee recommendations.

The third Panel meeting was held on January 21 and 22, 2003, to discuss the APCs of the newly implemented 2003 OPPS. We published a notice in the **Federal Register** on December 27, 2002 (67 FR 79107), to announce the following: The location and time of the third Panel meeting; a list of agenda items; and that the meeting was open to the public. In that document, we solicited public comment specifically on the items included on the agenda for the January 2003 Panel meeting. In this section, ''commenter'' refers to entities that provided comments in response to that **Federal Register** notice. We also provided additional information about the Panel meeting through a press release and on the CMS Web site. Presentations for the 2003 meeting met, at a minimum, the adopted guidelines for presentations referred to above.

3. Establishment of an Observation Subcommittee

At the third annual meeting in January 2003, the Panel suggested numerous changes to the APCs (listed below) and that a subcommittee be established to review observation issues, such as allowable International Classification of Diseases, clinical modification codes, and operational issues. Therefore, before the close of the third annual meeting, the Observation Subcommittee was established. Other Panel members that are not currently participating in this subcommittee are welcome to take part in this subcommittee, which is tasked with reviewing International Classification of Disease Codes, clinical modification codes, and operational issues related to observation. This subcommittee will report its findings to the Panel in 1 year.

4. Recommendations of the Advisory Panel and Our Responses

In this section, we consider the Panel's recommendations affecting specific APCs. The Panel based its recommendations on claims data for the period April 1, 2002 through September 30, 2002. This data set comprises a portion of the data that will be used to set 2004 payment rates. APC titles in this discussion are those that existed when the APC Panel met in January 2003. In a few cases, APC titles have been changed for this proposed rule, and, therefore, some APCs do not have the same title in Addendum A as they have in this section.

The Panel's agenda included APCs that our staff believe violate the 2 times rule as well as APCs for which comments were submitted. As discussed below, the Panel sometimes declined to recommend a change in an APC even though the APC appeared to violate the 2 times rule. In section II.B of this preamble, we discuss our proposals regarding the 2 times rule based on the April 1, 2002 through December 31, 2002 data that we used to determine the proposed 2004 APC relative weights. Section II.B also details the criteria we used when deciding to propose exceptions to the 2 times rule.

a. Debridement and Destruction.

APC 0012: Level I Debridement & Destruction.

APC 0013: Level II Debridement & Destruction.

We expressed concern to the Panel that APCs 0012 and 0013 appear to violate the 2 times rule. In order to remedy these violations, we asked the Panel to consider the following changes:

(1) Move the following codes from APC 0013 to APC 0012:

HCPCS	Description
11001	Debride infected skin add-on.
11302	Shave skin lesion.

HCPCS	Description
15786	Abrasion, lesion, single.
15793	Chemical peel, nonfacial.
15851	Removal of sutures.
16000	Initial treatment of burn(s).
16025	Treatment of burn(s).

(2) Move code 11057 (Trim skin lesions, over 4) from APC 0012 to APC 0013.

The Panel agreed with our staff and recommended that we make these changes. We propose to accept the Panel's recommendation.

b. 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 Panel that APCs 0019 and 0020 appear to violate the 2 times rule. In order to remedy these violations, we asked the Panel to consider the following changes:

(1) Move the following HCPCS codes from APC 0019 to a new APC:

HCPCS	Description
11755	Biopsy, nail unit.
11976	Removal of contraceptive cap.
24200	Removal of arm foreign body.
28190	Removal of foot foreign body.
56605	Biopsy of vulva/perineum.
56606	Biopsy of vulva/perineum.
69100	Biopsy of external ear.

(2) Move the following HCPCS codes from APC 0020 to APC 0021:

HCPCS	Description
11404	Removal of skin lesion.
11423	Removal of skin lesion.
11604	Removal of skin lesion.
11623	Removal of skin lesion.

The Panel recommended that we not change the structure of APCs 0019, 0020, and 0021 at this time in the interest of preserving clinical homogeneity. We propose to accept the Panel's recommendation that we make no changes to the structure of these APCs for 2004. We plan to place these APCs on the Panel's agenda for the 2005 update.

c. Thoracentesis/Lavage Procedures and Endoscopies.

APC 0071: Level I Endoscopy Upper Airway.

APC 0072: Level II Endoscopy Upper Airway.

APC 0073: Level III Endoscopy Upper Airway.

We expressed concern to the Panel that APCs 0071 and 0072 appear to violate the 2 times rule. In order to remedy these violations, we asked the Panel to consider the following changes:

Move the following HCPCS codes as described below:

TABLE 1.—HCPCS CODES PROPOSED TO BE REDISTRIBUTED FROM APCS 0071 AND 0072 TO APCS 0071, 0072, AND 0073

HCPCS	Description	2003 APC	2004 APC
31505	Diagnostic laryngoscopy	0072	0071
31575	Diagnostic laryngoscopy	0071	0072
31720	Clearance of airways	0072	0073

The Panel recommended that we make the above changes. We propose to accept the Panel's recommendation, with the exception of CPT code 31720. After reviewing an additional quarter of claims data that was not available at the time the Panel convened, placement of CPT code 31720 into APC 0072 better reflects its resource consumption. Therefore, we propose to keep CPT code 31720 in APC 0072.

d. Cardiac and Ambulatory Blood Pressure Monitoring.

APC 0097: Cardiac and Ambulatory Blood Pressure Monitoring.

We expressed concern to the Panel that APC 0097 appears to violate the 2 times rule. We asked the Panel to recommend options for resolving this violation, and suggested splitting APC 0097 into two APCs. The Panel recommended that the structure of APC 0097 should not be changed at this time based on clinical homogeneity considerations. We propose to accept the Panel's recommendation that we make no changes to APC 0097 for 2004. We plan to place this APC on the Panel's agenda for the 2005 update.

e. Electrocardiograms.

APC 0099: Electrocardiograms.

APC 0340: Minor Ancillary Procedures.

We expressed concern to the Panel that APC 0099 appears to violate the 2 times rule. We asked the Panel to recommend options for resolving this violation, and suggested moving CPT code 93701 (Bioimpedance, thoracic) from APC 0099 to APC 0340. The Panel felt, however, that the structure of APC 0099 should not be changed at this time based on clinical homogeneity considerations. We propose to accept the Panel's recommendation that we make no changes to APC 0099 for 2004. We plan to place this APC on the Panel's agenda for the 2005 update.

f. Cardiac Stress Tests.

APC 0100: Cardiac Stress Tests.

A presenter to the Panel, who represented a device manufacturer, requested that we move CPT code 93025 (Microvolt t-wave assessment) out of APC 0100. The presenter believes that the actual cost for this procedure is significantly higher than for other procedures in the same APC. Since this technology is often billed in conjunction with other procedures (for example, stress tests, CPT code 93017), few single-APC claims were available to evaluate the presenter's contention.

The Panel felt the data presented are insufficient to merit moving the code and recommends that CPT code 93025 remain in APC 0100 until more data are available for review. We propose to accept the Panel's recommendation that CPT code 93025 remain in APC 0100 until more claims data become available for review.

g. Revision/Removal of Pacemakers or Automatic Implantable Cardioverter Defibrillators.

APC 0105: Revision/Removal of Pacemakers, AICD, or Vascular.

We asked the Panel to review the codes within APC 0105 for an apparent violation of the 2 times rule, stating that we believe the apparent violation is a result of incorrectly coded claims. The Panel agreed and recommended no changes to APC 0105 at this time. We propose to accept the Panel's recommendation that we make no changes to APC 0105 until more accurate claims data become available and support the need for a change.

h. Sigmoidoscopy.

APC 0146: Level I Sigmoidoscopy.

APC 0147: Level II Sigmoidoscopy.

We expressed concern to the Panel that relatively simple procedures such as anoscopy and rigid sigmoidoscopy have higher median costs than more complex procedures such as flexible sigmoidoscopy. Panel members suggested the high costs may be due to the need to perform an otherwise minor office procedure in a hospital setting (for example, due to the clinical condition of the patient). Panel members also suggested that claims may be incorrectly coded because coding

instructions do not clearly state how to code when the procedure performed is not as extensive as the procedure planned (for example, when a colonoscopy is planned but only a sigmoidoscopy is performed). In these cases, coding instructions are unclear as to whether the planned procedure should be reported with a modifier for reduced services or with the code for the actual procedure performed.

The Panel recommended that we make no changes to APCs 0146 and 0147 at this time. We propose to accept the Panel's recommendation that we make no changes to APCs 0146 and 0147. We plan to place this APC on the Panel's agenda for the 2005 update.

i. Anal/Rectal Procedures.

APC 0148: Level I Anal/Rectal Procedure.

APC 0149: Level III Anal/Rectal Procedure.

APC 0155: Level II Anal/Rectal Procedure.

We expressed concern to the Panel that APCs 0148 and 0149 appear to violate the 2 times rule. We asked the Panel to recommend options for resolving these violations, and suggested rearranging some of the CPT codes within APCs 0148, 0149, and 0155. The Panel recommended that we move CPT code 46040 (Incision of rectal abscess) from APC 0155 to APC 0149. We propose to accept the Panel's recommendation.

j. Insertion of Penile Prosthesis.

APC 0179: Urinary Incontinence Procedures.

APC 0182: Insertion of Penile Prosthesis.

A presenter to the Panel representing manufacturers and providers requested that APC 0182 be split into two APCs, based on whether the procedure used inflatable or non-inflatable penile prostheses. The presenter stated that the complexity of the procedure, the cost of the devices, and related resources were all significantly higher with inflatable prostheses.

The Panel recommended that we eliminate APCs 0179 and 0182 and create two new APCs, 0385 and 0386 that contain the following CPT codes:

HCPCS	Description
APC 0385:	
52282	Cystoscopy, implant stent.
53440	Correct bladder function.
53444	Insert tandem cuff.
54400	Insert semi-rigid prosthesis.
54416	Remv/repl penis contain prosthesis.
APC 0386:	
53445	Insert uro/ves nck sphincter.
53447	Remove/replace ur sphincter.
54401	Insert self-contained prosthesis.
54405	Insert multi-comp penis prosthesis.
54410	Remove/replace penis prosthesis.

We propose to accept the Panel's recommendation to eliminate APCs 0179 and 0182 and create two new APCs, 0644 and 0645, containing the above CPT code configurations.

k. Surgical Hysteroscopy.

APC 0190: Surgical Hysteroscopy.

A presenter to the Panel, who represented a device manufacturer, requested that we move CPT code 58563 (Hysteroscopy, ablation) from APC 0190 to a higher paying APC. The presenter noted that endometrial cryoablation is included in a new technology APC, while a thermal ablation system is included with older, less costly techniques. The presenter expressed concern that cryoablation may be reimbursed at a higher rate than the thermal ablation system, giving its manufacturers an unfair competitive advantage.

Panel members agreed that new, more expensive technologies that prove to be more effective merit review for a higher payment rate. Without substantial evidence of greater effectiveness, however, the Panel was reluctant to create APCs that provide an incentive to use a more expensive device. In its discussion of whether or not to recommend moving CPT code 58563 to a higher paying APC, the Panel recommended that we take into account different methods of endometrial ablation associated with hysteroscopy, adequately reflect the resources used for the various procedures, avoid creating a competitive advantage or disadvantage, and collect data needed to track costs on the type of technologies used for this procedure.

After consulting with experts in the field, we propose to split APC 0190 (Surgical Hysteroscopy) into 2 APCs that are more clinically homogeneous. We propose to change the description for APC 0190 from ''Surgical Hysteroscopy'' to ''Level I Hysteroscopy'' and keep the following HCPCS codes in APC 0190:

HCPCS	Description
58558	Hysteroscopy, biopsy.
58559	Hysteroscopy, lysis.
58562	Hysteroscopy, remove fb.
58579	Hysteroscope procedure.

We also propose to move the following HCPCS codes from APC 0190 to newly created APC 0387 titled ''Level II Hysteroscopy'':

HCPCS	Description
58560	Hysteroscopy, resect septum.
58561	Hysteroscopy, remove myoma.
58563	Hysteroscopy, ablation.

In addition, we propose to move the following HCPCS codes as described below:

TABLE 2.—HCPCS CODES PROPOSED TO BE REDISTRIBUTED TO APCS 0130, 0195, AND 0190

HCPCS	Description	2003 APC	2004 APC
58578	Laparoscopic procedure, uterus	0190	0130
58353	Endometrial ablate, thermal	0193	0195
58555	Hysteroscopy, diagnostic, sep. procedure	0194	0190

We believe these proposed changes take into account the different technologies used to perform these procedures while maintaining the clinical comparability of these APCs as well as improving their homogeneity in terms of resource consumption.

l. Female Reproductive Procedures.

APC 0195: Level VII Female Reproductive Proc. APC 0202: Level VIII Female Reproductive Proc.

A commenter requested that we place CPT code 57288 (Repair bladder defect) in its own APC because it requires the use of a device. Our staff suggested that CPT codes 57288 and 57287 remain in APC 0202, while the remaining codes in APC 0202 be moved to APC 0195:

HCPCS	Description
57109	Vaginectomy partial w/nodes.
58920	Partial removal of ovary(s).
58925	Removal of ovarian cyst(s).

The Panel agreed with our staff, and we propose to accept the Panel's recommendation to move CPT codes

57109, 58920, and 58925 from APC 0202 to APC 0195.

m. Nerve Injections.

APC 0203: Level IV Nerve Injections.

APC 0204: Level I Nerve Injections.

APC 0206: Level II Nerve Injections.

APC 0207: Level III Nerve Injections.

Several commenters suggested changes in the configuration of APCs 0203, 0204, 0206, and 0207 because of concerns that the current classifications result in payment rates that are too low relative to the resource costs associated with certain procedures in these APCs. Several of these APCs include procedures associated with drugs or devices for which pass-through payments are scheduled to expire in 2003.

We requested the Panel's input regarding whether or not these APCs should be restructured. The Panel stated that the current configuration of APCs 0203, 0204, 0206, and 0207 is more clinically cohesive than the previous year's configuration and that more data should be collected before making any changes. We propose to accept the Panel's recommendation that we make no changes to the structure of these APCs until more data become available for review.

n. Laminotomies and Laminectomies; Implantation of Pain Management Device.

APC 0208: Laminotomies and Laminectomies.

APC 0223: Implantation of Pain Management Device.

A presenter to the Panel, who represented a device manufacturer, requested that we move CPT code 62351 (Implant spinal canal catheter) from APC 0208 to APC 0223 to better capture the device cost that may be involved with the procedure. The Panel felt the data were insufficient to merit moving the code and recommended that CPT code 62351 remain in APC 0208 until more data are available for review. We propose to accept the Panel's recommendation that CPT code 62351 remain in APC 0208 until more claims data become available for review.

o. Extended EEG Studies and Sleep Studies; Electroencephalogram.

APC 0209: Extended EEG Studies and Sleep Studies, Level II.

APC 0213: Extended EEG Studies and Sleep Studies, Level I.

APC 0214: Electroencephalogram.

We expressed concern to the Panel that APC 0213 appears to minimally violate the 2 times rule. In order to remedy this violation, we asked the Panel to consider a commenter's suggestion that we move CPT code 95955 (EEG during surgery) from APC 0214 to APC 0213. The Panel agreed with the commenter's suggestion. We propose to accept the Panel's recommendation to move CPT code 95955 from APC 0214 to APC 0213.

p. Nerve and Muscle Tests.

APC 0215: Level I Nerve and Muscle Tests.

APC 0216: Level III Nerve and Muscle Tests.

APC 0218: Level II Nerve and Muscle Tests.

We expressed concern to the Panel that APC 0218 appears to violate the 2 times rule. In order to remedy this violation, one commenter requested that we move CPT codes 95921 (Autonomic nerve function test) and 95922 (Autonomic nerve function test) from APC 0218 to APC 0216, while another commenter requested that we move CPT code 95904 (Sensory nerve conduction test) from APC 0215 to APC 0218. Alternatively, our staff suggested to the Panel that the following CPT codes be moved from APC 0218 to APC 0215.

HCPCS	Description
95858	Tensilon test & myogram.
95870	Muscle test, nonparaspinal.
95900	Motor nerve conduction test.
95903	Motor nerve conduction test.

After considering all of the above proposals, the Panel recommended that we move CPT codes 95858, 95870, 95900, and 95903 from APC 0218 to APC 0215. We propose to accept the Panel's recommendation.

q. Implantation of Drug Infusion Device.

APC 0227: Implantation of Drug Infusion Device.

APC 0227 contains only two CPT codes: one for implantation of programmable spine infusion pumps, 62362, and for implantation of non-programmable spine infusion pumps, 62361. A commenter requested that we split APC 0227 into two APCs to recognize the cost difference between CPT code 62361 and CPT code 62362. However, since our cost data do not show a significant cost difference between the two devices and APC 227 does not violate the 2 times rule, the Panel recommended that CPT codes 62361 and 62362 remain in APC 0227. We propose to accept the Panel's recommendation.

r. Ophthalmologic APCs.

APC 0230: Level I Eye Tests & Treatments.

APC 0235: Level I Posterior Segment Eye Procedures.

APC 0236: Level II Posterior Segment Eye Procedures.

APC 0698: Level II Eye Tests & Treatments.

We advised the Panel that APCs 0230 and 0235 violate the 2 times rule but that the current configuration of these APCs reflects the Panel's previous recommendations. A presenter to the Panel, who represented a device manufacturer, expressed concern that the pass-through device category ''New Technology: Intraocular Lens'' was discontinued and these devices are now packaged. The presenter asked the Panel to recommend that future new intraocular lens devices be considered for a new pass-through category.

To remedy the violations to the 2 times rule, we asked the Panel to consider moving CPT code 67820 (Revise eyelashes) from APC 0230 to APC 0698 and CPT code 67110 (Repair detached retina) from APC 0235 to APC 0236. The Panel recommended that we make these changes. We propose to accept the Panel's recommendation and monitor the data for APC 0235 for possible review next year. The Panel also acknowledged that making recommendations concerning pass-through categories is beyond their purview.

s. Skin Tests and Miscellaneous Red Blood Cell Tests; Transfusion Laboratory Procedures.

APC 0341: Skin Tests and Miscellaneous Red Blood Cell Tests.

APC 0345: Level I Transfusion Laboratory Procedures.

We advised the Panel that APCs 0341 and 0345 minimally violate the 2 times rule and suggested moving several CPT codes within these APCs into a new APC because a commenter expressed concern over the combination of skin tests and miscellaneous red blood cell tests in APC 0341, asserting that services within this APC cannot be considered comparable with respect to resource usage.

In order to remedy these violations to the 2 times rule, we suggested moving CPT code 86901 (Blood typing, Rh (D)) from APC 0345 to a new APC along with the following CPT codes from APC 0341:

HCPCS	Description
86880	Coombs test, direct.
86885	Coombs test, indirect, qualitative.
86886	Coombs test, indirect, titer.
86900	Blood typing, ABO.

The Panel recommended that we make the above changes. We propose to accept the Panel's recommendation to move HCPCS codes 86880, 86885, 86886, and 86900 from APC 0341 to new APC 0409 and to move CPT code 86901 (Blood typing, Rh (D)) from APC 0345 to new APC 0409.

t. Otorhinolaryngologic Function Tests.

APC 0363: Level I Otorhinolaryngologic Function Tests.

APC 0660: Level II Otorhinolaryngologic Function Tests.

We expressed concern to the Panel that APC 0660 appears to violate the 2 times rule and suggested moving CPT codes 92543 (Caloric vestibular test) and 92588 (Evoked auditory test) from APC 0660 to APC 0363. The Panel recommended that we make these CPT code changes. We propose to accept the Panel's recommendation to move CPT codes 92543 and 92588 from APC 0660 to APC 0363.

u. Tube Changes and Repositioning.

APC 0121: Level I Tube changes and Repositioning

APC 0122: Level II Tube changes and Repositioning

We expressed concern to the Panel that APC 0121 appears to violate the 2 times rule. In order to remedy this violation, we suggested moving the following CPT codes from APC 0121 to APC 0122:

HCPCS	Description
47530	Revise/reinsert bile tube.
50688	Change of ureter tube.
51710	Change of bladder tube.
62225	Replace/irrigate catheter.

The Panel recommended that we make these CPT code changes. We propose to accept the Panel's recommendation to move CPT codes 47530, 50688, 51710, and 62225 from APC 0121 to APC 0122.

v. Myelography.

APC 0274: Myelography.

We advised the Panel that APC 0274 minimally violates the 2 times rule and suggested moving CPT codes 72285 (X-ray c/t spine disk) and 72295 (X-ray c/t spine disk) from APC 0274 to a new APC. A presenter, from an organization representing radiologists, agreed with our proposal. The Panel recommended that we make these CPT code changes. We propose to accept the Panel's recommendation to move CPT codes 72285 and 72295 from APC 0274 to new APC 0388.

w. Therapeutic Radiologic Procedures.

APC 0296: Level I Therapeutic Radiologic Procedures

APC 0297: Level II Therapeutic Radiologic Procedures

We advised the Panel that APCs 0296 and 0297 appear to minimally violate the 2 times rule as a result of changes recommended by the Panel and adopted by CMS last year. The Panel recommended that no changes be made to APCs 0296 and 0297 in the interest of preserving the clinical homogeneity of these APCs. We propose to accept the Panel's recommendation that we make no CPT code changes to APCs 0296 and 0297.

x. Vascular Procedures; Cannula/Access Device Procedures.

APC 0103: Miscellaneous Vascular Procedures

APC 0115: Cannula/Access Device Procedures

A commenter requested that we move CPT code 36860 (External cannula declotting) from APC 0103 to APC 0115, asserting that this procedure is more similar to other procedures in APC 0115 and does not fit well in its current miscellaneous APC. The Panel found that the claims data were insufficient to support moving CPT code 36860 from APC 0103 to the higher paying APC 0115 and recommends that CPT code 36860 remain in APC 0103 until more data are available for review. We propose to accept the Panel's recommendation that CPT code 36860 remain in APC 0103 until more claims data become available for review.

y. 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.

A commenter 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. A presenter to the Panel testified that CPT code 75978 is commonly used for dialysis patients and often requires multiple intraoperative attempts to succeed; thus, it should be paid under APC 280. The Panel felt that APCs 0279, 0280, and 0668 were clinically homogenous and recommended that we only make changes after consulting with experts in the field. We propose to accept the Panel's recommendation to make no changes to APCs 0279, 0280, and 0668 until consulting with experts in the field. We plan to place these APCs on the Panel's agenda for the 2005 update.

z. Computed Tomography (CT), Magnetic Resonance (MR), and Ultrasound Guidance Procedures Currently Packaged.

APC 0332: Computerized Axial Tomography and Computerized Angiography without Contrast Material.

APC 0335: Magnetic Resonance Imaging, Miscellaneous.

APC 0268: Ultrasound Guidance Procedures.

A presenter to the Panel expressed concern that the packaging of guidance procedures for tissue ablation does not recognize the significant difference in cost and time required to perform each procedure (for example, MRI vs. CT). This presenter felt that hospitals needed more education on the appropriate application of these codes. Another commenter requested that CPT codes 76362, 76394, and 76490 be changed from a status indicator of N to a status indicator of S and included in an appropriate clinical or new technology APC.

The Panel agreed with the above comments and stated that the packaging of these three procedures made it difficult for hospitals to track their use for the purpose of allocating funds. The Panel recommended changing the following CPT codes from a packaged status (N status indicator) to a separately payable status (S status indicator) within the indicated APCs:

TABLE 3.—HCPCS CODES PROPOSED TO BE DESIGNATED AS SEPARATELY PAYABLE

HCPCS	Description	2003 status	2004 APC
76362	CT scan for tissue ablation	Packaged	0332
76394	MRI for tissue ablation	Packaged	0335
76490	US for tissue ablation	Packaged	0268

We propose to accept the Panel's recommendation to change HCPCS codes 76362, 76394, and 76490 from a packaged status to a separately payable status as indicated above.

aa. Magnetic Resonance Imaging and Magnetic Resonance Angiography Without Contrast.

APC 0336: Magnetic Resonance Imaging and Magnetic Resonance Angiography without Contrast

A commenter requested that we change CPT code 76393 (MR guidance for needle placement) from a packaged status to a separately payable status within APC 0336. Based on clinical homogeneity considerations, the Panel agreed with the commenter and recommended that CPT code 76393 be changed from a status indicator of N to a status indicator of S and placed in APC 0335. We propose to accept the Panel's recommendation.

bb. Plain Film Except Teeth; Plain Film Except Teeth Including Bone Density Measurement.

APC 0260: Level I Plain Film Except Teeth.

APC 0261: Level II Plain Film Except Teeth Including Bone Density Measurement.

APC 0272: Level I Fluoroscopy.

A commenter requested that we move CPT codes 76120 (Cine/video x-rays) and 76125 (Cine/video x-rays add-on) from APC 0260 to APC 0261. However, a presenter to the Panel argued that these CPT codes are fluoroscopic procedures that should not be grouped with Level I radiography procedures. The Panel recommended that we move CPT code 76120 from APC 0260 to APC 0272 and that CPT code 76125 remain in APC 0260. This change makes the APCs more clinically coherent. We propose to accept the Panel's recommendation.

cc. Chemotherapy Administration by Other Technique Except Infusion.

APC 0116: Chemotherapy Administration by Other Technique Except Infusion.

A presenter to the Panel requested that we split APC 0116 into three APCs according to the method of administration: (a) Subcutaneous or intramuscular administration (CPT code 96400); (b) ''push'' administration (CPT code 96408); and (c) central nervous system administration (CPT code 96450). The presenter also requested that existing CPT codes should replace the more nonspecific Q codes for administration of chemotherapy because the CPT codes would provide more detailed data on methods of chemotherapy administration, which could be used for future payment policy decisions. Another presenter agreed with this request and stated that CPT codes are preferable to Q codes because other payers require CPT codes.

The Panel agreed with the above suggestions to split APC 0116 into 3 APCs according to the method of administration. The Panel recommended that we require hospitals to use the existing CPT codes (for example, 96400, 96408, and 96450) for administration of chemotherapy and map them to APCs 0116, 0117, and 0118, as appropriate. The Panel also recommended that payment rates be based on current Q code cost data until cost data for the CPT codes are available. These cost data would be used to determine whether to change the APC structure for chemotherapy administration.

We propose not to accept the Panel's recommendations to split APC 0116 into 3 APCs and to use CPT codes for administration of chemotherapy. We would consider such a split in the future but would like to first address the administration of drugs issue. We believe that making a change in APC 116 would be too complicated for hospitals given the changes for administration in general that we are considering in this proposed rule for implementation in CY 2004. We will consider such a split for APC 116 for CY 2005. We also believe the use of CPT codes would be burdensome to hospitals, would require extensive education, and would result in a significant amount of miscoding. The CPT codes for infusion therapy are based on the service furnished per hour. We do not believe that all hospitals routinely record the start and stop time for infusion therapy and that doing so in order to be able to bill the proper number of hours of infusion therapy could be very burdensome for them. Moreover, the historic cost data on which we base the payment for the service is reported on a per visit basis (much easier to cull from the record than the number of hours of service) and if we changed to CPT codes for these services, we would be unable to convert the charge/cost data now on a per visit basis to a per hour basis (as required by the CPT code) for budget neutrality purposes. Please see section VI of this proposed rule for further discussion on payments for drugs and drug administration.

dd. Capturing the Costs of Drugs and Biologicals Packaged Into APCs.

APC 0290: Level I Diagnostic Nuclear Medicine Excluding Myocardial Scans.

APC 0291: Level II Diagnostic Nuclear Medicine Excluding Myocardial Scans.

APC 0292: Level III Diagnostic Nuclear Medicine Excluding Myocardial Scans.

APC 0294: Level II Therapeutic Nuclear Medicine.

APC 0666: Myocardial Add-on Scans.

We told the Panel that APCs 0290 and 0291 appear to violate the 2 times rule. Several presenters to the Panel expressed concern that our cost data are inadequate because of confusion over coding due to changes in codes and coding instructions for these procedures, poor hospital reporting of radiopharmaceutical use, and the use of single (not multiple) claims in determining costs. One presenter claimed that the current cost data used for CPT code 78122 (Whole blood volume determination) underestimated real costs because of confusion about whether to code radiopharmaceuticals on a ''per dose'' basis or ''per millicurie'' basis. This presenter requested that we move CPT code 78122 from APC 0290 to the higher paying APC 0292.

Other presenters agreed with these concerns and said they were applicable to payments for all drugs, not just radiopharmaceuticals. These commenters were also concerned about the loss of drug-specific data due to packaging because hospitals would have no incentive to code, and thereby, identify, packaged drugs.

Pass-through payments for 236 drugs, biologicals, and radiopharmaceuticals expired as of 2003, and these items are now paid either separately or packaged with the procedures with which they are associated. Drugs and radiopharmaceuticals with median costs for administration of $150 or less were packaged. Beginning in 2003 claims data will not provide specific cost information for packaged items. We requested input from the Panel for methods to determine drug costs.

Panel members were concerned that packaging the costs of radiopharmaceuticals into procedures would result in underpayments for the service because we lack adequate data on the cost of radiopharmaceuticals. They were also concerned about creating incentives to use radiopharmaceuticals based on cost rather than clinical efficacy. The Panel recommended that we consider grouping drugs and radiopharmaceuticals into new APCs taking into account both their cost and clinical use. The Panel further recommended that, if new APCs for radionucliides are created, the descriptors should be as simple as possible and use of confusing units of measure should be limited.

Due to the packaging of radiopharmaceuticals into the APC payments for nuclear medicine procedures, we, along with commenters have expressed concern to the Panel regarding whether the current nuclear medicine APC structure is homogeneous in terms of resource consumption. We have reviewed information about the use and cost of various

radiopharmaceuticals and believe that reorganizing the APCs for nuclear medicine would result in greater clinical and resource homogeneity. Therefore, we propose to eliminate APCs 0286, 0290, 0291, 0292, 0294, 0666 and create 20 new APCs for nuclear medicine that contain the following CPT codes:

HCPCS	Description
APC 0389:	
78000	Thyroid, single uptake.
78001	Thyroid, multiple uptakes.
78003	Thyroid suppress/stimul.
78020	Thyroid met uptake.
78099	Endocrine nuclear procedure.
78190	Platelet survival, kinetics.
78191	Platelet survival.
78199	Blood/lymph nuclear exam.
78299	GI nuclear procedure.
78399	Musculoskeletal nuclear exam.
78499	Cardiovascular nuclear exam.
78599	Respiratory nuclear exam.
78699	Nervous system nuclear exam.
78725	Kidney function study.
78799	Genitourinary nuclear exam.
78999	Nuclear diagnostic exam.
79999	Nuclear medicine therapy.
APC 0390:	
78006	Thyroid imaging with uptake.
78010	Thyroid imaging.
78015	Thyroid met imaging.
78016	Thyroid met imaging/studies.
APC 0391:	
78007	Thyroid image, mult uptakes.
78011	Thyroid imaging with flow.
78018	Thyroid met imaging, body.
78070	Parathyroid nuclear imaging.
APC 0392:	
78075	Adrenal nuclear imaging.
APC 0393:	
78110	Plasma volume, single.
78111	Plasma volume, multiple.
78120	Red cell mass, single.
78121	Red cell mass, multiple.
78122	Blood volume.
78130	Red cell survival study.
78135	Red cell survival kinetics.
78140	Red cell sequestration.
78160	Plasma iron turnover.
78162	Radioiron absorption exam.
78170	Red cell iron utilization.
78172	Total body iron estimation.
APC 0400:	
78102	Bone marrow imaging, ltd.
78103	Bone marrow imaging, mult.
78104	Bone marrow imaging, body.
78185	Spleen imaging.
78195	Lymph system imaging.
APC 0394:	
78201	Liver imaging.
78202	Liver imaging with flow.
78205	Liver imaging (3D).
78206	Liver image (3d) with flow.
78215	Liver and spleen imaging.
78216	Liver & spleen image/flow.
78220	Liver function study.
78223	Hepatobiliary imaging.
APC 0395:	
78230	Salivary gland imaging.
78231	Serial salivary imaging.
78232	Salivary gland function exam.
78258	Esophageal motility study.
78261	Gastric mucosa imaging.
78262	Gastroesophageal reflux exam.
78264	Gastric emptying study.
78278	Acute GI blood loss imaging.
78290	Meckel's divert exam.
78291	Leveen/shunt patency exam.
78270	Vit B–12 absorption exam.
78271	Vit b-12 absrp exam, int fac.
78272	Vit B–12 absorp, combined.
78282	GI protein loss exam.
APC 0396:	
78300	Bone imaging, limited area.
78305	Bone imaging, multiple areas.
78306	Bone imaging, whole body.
78315	Bone imaging, 3 phase.
78320	Bone imaging (3D).
APC 0397:	
78414	Non-imaging heart function.
78445	Venous thrombosis study.
78455	Venous thrombosis study.
78456	Acute venous thrombus image.
78457	Venous thrombosis imaging.
78458	Ven thrombosis images, bilat.
APC 0398:	
78428	Cardiac shunt imaging.
78460	Heart muscle blood, single.
78461	Heart muscle blood, multiple.
78464	Heart image (3d), single.
78465	Heart image (3d), multiple.
78466	Heart infarct image.
78468	Heart infarct image (ef).
78469	Heart infarct image (3D).
78472	Gated heart, planar, single.
78473	Gated heart, multiple.
78481	Heart first pass, single.
78483	Heart first pass, multiple.
78494	Heart image, spect.
APC 0399:	
78478	Heart wall motion add-on.
78480	Heart function add-on.
78496	Heart first pass add-on.
APC 0401:	
78580	Lung perfusion imaging.
78584	Lung V/Q image single breath.
78585	Lung V/Q imaging.
78586	Aerosol lung image, single.
78587	Aerosol lung image, multiple.
78588	Perfusion lung image.
78591	Vent image, 1 breath, 1 proj.
78593	Vent image, 1 proj, gas.
78594	Vent image, mult proj, gas.
78596	Lung differential function.
APC 0402:	
78600	Brain imaging, ltd static.
78601	Brain imaging, ltd w/flow.
78605	Brain imaging, complete.
78606	Brain imaging, compl w/flow.
78607	Brain imaging (3D).
78610	Brain flow imaging only.
78615	Cerebral vascular flow image.
APC 0403:	
78630	Cerebrospinal fluid scan.
78635	CSF ventriculography.
78645	CSF shunt evaluation.
78647	Cerebrospinal fluid scan.
78650	CSF leakage imaging.
78660	Nuclear exam of tear flow.
APC 0404:	
78700	Kidney imaging, static.
78701	Kidney imaging with flow.
78704	Imaging renogram.
78707	Kidney flow/function image.
78708	Kidney flow/function image.
78709	Kidney flow/function image.
78710	Kidney imaging (3D).
78715	Renal vascular flow exam.
APC 0405:	
78730	Urinary bladder retention.
78740	Ureteral reflux study.
78760	Testicular imaging.
78761	Testicular imaging/flow.
APC 0406:	
78800	Tumor imaging, limited area.
78801	Tumor imaging, mult areas.
78802	Tumor imaging, whole body.
78803	Tumor imaging, whole body.
78805	Abscess imaging, ltd area.
78806	Abscess imaging, whole body.
78807	Nuclear localization/abscess.
G0273	Pretx planning, non-Hodgkins.
APC 0407:	
79000	Init hyperthyroid therapy.
79001	Repeat hyperthyroid therapy.
79020	Thyroid ablation.
79030	Thyroid ablation, carcinoma.
79035	Thyroid metastatic therapy.
APC 0408:	
79100	Hematopoetic nuclear therapy.
79200	Intracavitary nuclear trmt.
79300	Interstitial nuclear therapy.
79400	Nonhemato nuclear therapy.
79420	Thyroid metastatic therapy.
79440	Nuclear joint therapy.
G0274	Radiopharm tx, non-Hodgkins.

We believe that the proposed APC structure, which takes into account the organ(s) being examined (or treated) as well as the type and complexity of the procedure, is more homogeneous both clinically and in terms of resource consumption than the current APC structure.

Currently, payment for the radiopharmaceutical ''zevalin'' (Ibritumomab Tiuxetan) is packaged into the payment for HCPCS codes G0273 (Pretx planning, non-Hodgkins) and G0274 (Radiopharm tx, non-Hodgkins). To ensure consistency with our payment policy for other radiopharmaceuticals (that is, making separate payment for radiopharmaceuticals whose costs are greater than $150 per episode of care), we are proposing to make payment for ''zevalin'' (Ibritumomab Tiuxetan) separately from payment for the procedures with which ''zevalin'' (Ibritumomab Tiuxetan) is used.

We propose to use HCPCS A9522 (Indium 111 ibritumomab tiuxetan) to report the use of In-111 Zevalin (In-111 Ibritumomab Tiuxetan) and HCPCS A9523 (Yttrium 90 ibritumomab tiuxetan) to report the use of Y90 Zevalin (Y90 Ibritumomab Tiuxetan). We would place HCPCS A9522 in APC 9118 with a payment amount of $2,084.55 and HCPCS A9523 in APC 9117 with a payment amount of $18,066.09. We note that payment rates for radiopharmaceuticals are not subject to wage index adjustments because no

portion of the payment is attributed to labor-related costs.

Because we propose that payment for G0273 and G0274 no longer include payment for ''zevalin,'' we also propose to place G0273 into newly created APC 0406 and G0274 into newly created APC 0408. These APCs include procedures that are similar clinically and in terms of resource consumption to G0274 and G0273, respectively.

Please see section VI of this proposed rule for further discussion on payments for drugs, biologicals, and radiopharmaceuticals.

ee. Endoscopy Lower Airway.

APC 0076: Endoscopy Lower Airway.

A presenter to the Panel expressed concern that APC 0076 apparently violates the 2 times rule and requested that we move CPT code 31631 (bronchoscopy with tracheal stent placement) from APC 0076 and into a new APC.

The Panel suggested that a new APC comprised of the four most costly procedures in APC 0076 would result in a more homogenous grouping, and recommended that we move the following CPT codes from APC 0076 and into newly created APC 0415.

HCPCS	Description
31630	Bronchoscopy dilate/fracture reduction.
31631	Bronchoscopy, dilate w/stent.
31640	Bronchoscopy w/tumor excise.
31641	Bronchoscopy, treat blockage.

We propose to accept the Panel's recommendation that we move CPT codes 31630, 31631, 31640, and 31641 from APC 0076 to new APC 0415.

ff. Gastrointestinal Endoscopic Stenting Procedures.

APC 0141: Upper GI Procedures.

APC 0142: Small Intestine Endoscopy.

APC 0143: Lower GI Endoscopy.

APC 0147: Level II Sigmoidoscopy.

A commenter requested that we create a new APC that would be comprised of all the gastrointestinal endoscopic stent codes. The Panel agreed with the commenter's suggestion because the resource requirements for all gastrointestinal endoscopic stents appear to be similar.

The Panel recommended that we move the following CPT codes from their 2003 APCs to newly created APC 0384 for 2004:

TABLE 4.—HCPCS CODES TO BE MOVED INTO NEW APC 0646

HCPCS	Description	2003 APC	2004 APC
43219	Esophagus endoscopy	0141	0384
43256	Upper GI endoscopy w/stent	0141	0384
44370	Small bowel endoscopy w/stent	0142	0384
44379	Small bowel endoscopy w/stent	0142	0384
44383	Small bowel endoscopy	0142	0384
44397	Colonoscopy w/stent	0143	0384
45387	Colonoscopy w/stent	0143	0384
45327	Proctosigmoidoscopy w/stent	0147	0384
45345	Sigmoidoscopy w/stent	0147	0384

We propose to accept the Panel's recommendation to move the following gastrointestinal endoscopic stent CPT codes into newly created APC 0384: 43219, 43256 (from APC 0141); 44370, 44379, 44383 (from APC 0142); 44397, 45387 (from APC 0143); 45327, and 45345 (from APC 0147).

gg. Capturing the Costs of Devices That Are Packaged Into APCs.

APC 0081: Non-Coronary Angioplasty or Atherectomy.

APC 0083: Coronary Angioplasty and Percutaneous Valvuloplasty.

APC 0104: Transcatheter Placement of Intracoronary Stents.

APC 0222: Implantation of Neurological Device.

APC 0223: Implantation of Pain Management Device.

APC 0227: Implantation of Drug Infusion Device.

APC 0229: Transcatheter Placement of Intravascular Shunts.

Several commenters requested that the status indicators for the above APCs (all of which include high-cost devices) be changed from T (multiple-procedure discount applies) to S (multiple-procedure discount does not apply). Two presenters to the Panel stated that hospitals do not pay less for devices when they are used in the context of a multiple-procedure claim and suggested that we apply the multiple-procedure reduction to the non-device portion of the claim only. Alternatively, these presenters recommended that we apply the discount policy only when the device cost is below a predetermined proportion of the APC cost. Another presenter to the Panel requested that APCs 0222, 0223, and 0227 be exempt from the multiple procedure discount policy because the cost of the devices used in these procedures makes up more than 50 percent of the APC cost.

We sought the Panel's input as to whether there are situations in which we should not apply our multiple procedure discount policy. The Panel recommended no changes to the status indicators for any of the device-related APCs discussed because they were concerned that exemptions from the discount policy could result in incentives to use more devices than necessary. However, the Panel asked that we analyze our data to determine if we may be underpaying for devices when the multiple procedure discounting policy is applied and recommended that we develop some methodology to track device costs. In section V.C of this proposed rule, we discuss the issue of device costs and multiple procedure reductions and our progress to date in developing ''combination APCs'' to address the Panel's concern.

hh. Discussion of Ways To Increase the Use of Multiple Claims To Set APC Payment Rates.

A presenter to the Panel suggested that we use dates of service on multiple procedure claims to increase the number of claims we use to set payment rates. Another presenter suggested that we could further increase the number of multiple procedure claims that could be used to set payment rates by ignoring codes with status indicator K. Other suggestions were to exclude from consideration those APCs with small dollar values and to create a new code or APC specifically for the insertion and removal of devices.

The Panel recommended that our staff explore ways to increase the number of claims used to set payment rates, including the following methodologies: sort multiple claims by date of service; exclude codes with K status indicator from evaluation; exclude those APCs with nominal costs (the definition of ''nominal'' can be determined by

modeling a variety of possible dollar amounts). In addition, the Panel recommended that we create no G codes as part of the effort to use multiple procedure claims for developing relative weights. If new codes are needed, the Panel suggested that our staff work with the American Medical Association's CPT Board to identify possible new codes. Please see section V.C of this proposed rule for our discussion of the use of multiple procedure claims for developing payment rates for procedures that use devices.

B. Other Changes Affecting the APCs

1. Limit on Variation of Costs of Services Classified Within an APC Group

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 highest cost item or service within an APC group is more than 2 times greater than the lowest cost item or service within the 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.

Taking into account the proposed APC changes discussed in relation to the APC Panel recommendations in section II.A.4 of this proposed rule and the use of 2002 claims data to calculate the median cost of procedures classified to APCs, we reviewed all the APCs to determine which of them would not meet the 2 times limit. We use the following criteria when deciding whether to make exceptions to the 2 times rule for affected APCs:

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

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

The following table contains APCs that we propose 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 Panel recommendation because Panel recommendations were based on explicit consideration of resource use, clinical homogeneity, hospital specialization, and the quality of the data used to determine payment rates.

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 5.—TABLE OF APCS EXEMPTED FROM 2 TIMES RULE

Proposed rule APC	Description
0004	Level I Needle Biopsy/Aspiration Except Bone Marrow.
0018	Biopsy of Skin/Puncture of Lesion.
0019	Level I Excision/Biopsy.
0020	Level II Excision/Biopsy.
0032	Insertion of Central Venous/Arterial Catheter.
0043	Closed Treatment Fracture Finger/Toe/Trunk.
0046	Open/Percutaneous Treatment Fracture or Dislocation.
0048	Arthroplasty with Prosthesis.
0055	Level I Foot Musculoskeletal Procedures.
0058	Level I Strapping and Cast Application.
0060	Manipulation Therapy.
0072	Level II Endoscopy Upper Airway.
0073	Level III Endoscopy Upper Airway.
0080	Diagnostic Cardiac Catheterization.
0084	Level I Electrophysiologic Evaluation.
0097	Cardiac and Ambulatory Blood Pressure Monitoring.
0099	Electrocardiograms.
0105	Revision/Removal of Pacemakers, AICD, or Vascular.
0130	Level I Laparoscopy.
0147	Level II Sigmoidoscopy.
0148	Level I Anal/Rectal Procedure.
0155	Level II Anal/Rectal Procedure.
0164	Level I Urinary and Anal Procedures.
0165	Level III Urinary and Anal Procedures.
0192	Level IV Female Reproductive Proc.
0203	Level IV Nerve Injections
0204	Level I Nerve Injections.
0207	Level III Nerve Injections.
0213	Extended EEG Studies and Sleep Studies, Level I.
0214	Electroencephalogram.
0218	Level II Nerve and Muscle Tests.
0231	Level III Eye Tests & Treatments.
0233	Level II Anterior Segment Eye Procedures.
0235	Level I Posterior Segment Eye Procedures.
0239	Level II Repair and Plastic Eye Procedures.
0245	Level I Cataract Procedures without IOL Insert.
0252	Level II ENT Procedures.
0262	Plain Film of Teeth.
0266	Level II Diagnostic Ultrasound Except Vascular.
0274	Myelography.
0303	Treatment Device Construction.
0330	Dental Procedures.
0340	Minor Ancillary Procedures.

TABLE 5.—TABLE OF APCS EXEMPTED FROM 2 TIMES RULE—Continued

Proposed rule APC	Description
0341	Skin Tests.
0344	Level III Pathology.
0363	Level I Otorhinolaryngologic Function Tests.
0364	Level I Audiometry.
0367	Level I Pulmonary Test.
0368	Level II Pulmonary Tests.
0370	Allergy Tests.
0373	Neuropsychological Testing.
0385	Urinary Incontinence Procedures.
0397	Vascular Imaging.
0408	Non-thyroid Radionucliide Treatment.
0409	Red Blood Cell Tests.
0600	Low Level Clinic Visits.
0668	Level I Angiography and Venography except Extremity.
0692	Electronic Analysis of Neurostimulator Pulse Generators.
0698	Level II Eye Tests & Treatments.

2. Procedures Moved From New Technology APCs to Clinically Appropriate APCs

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 time frame that new technology APCs would be in effect (65 FR 18457). Beginning in 2002, we retain a service within a new technology APC group 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 context of new technology procedures, we create HCPCS codes for services only. We do not create HCPCS codes for equipment that is used in the course of providing an item or service (except in the case of ''C'' codes for devices that meet the criteria for transitional pass-through payments). Equipment that is used to provide an item or service is not separately coded because it is a resource required to furnish the service. Like other resources that are required to furnish a service (for example, cost of a room, cost of staff, cost of supplies), the hospital should show charges either as part of its charge for the procedure or with a revenue code.

As described in more detail below, we propose to delete four HCPCS codes that are currently paid in new technology APCs. These four HCPCS codes do not conform to our current policy to not create HCPCS codes for equipment used to provide a service. In addition, there exist, or soon will exist, CPT codes to describe the services being furnished, including any equipment that is needed to perform them, so we believe it is appropriate at this time to delete the HCPCS codes. The HCPCS codes we propose to delete effective January 1, 2004 are:

C1088: Laser Optic Treatment system, Indigo Laseroptic Treatment System,

C9701: Stretta System,

C9703: Bard Endoscopic Suturing System, and

C9711: H.E.L.P. Apheresis System.

These codes were created and assigned to New Technology APCs when it was CMS policy to create a C code to describe an item of equipment for which there was no other means of making payment for the service in which the equipment was used. In the November 30, 2001 final rule, we announced that we would not use New Technology APCs to pay for drugs, devices, and equipment that are used in the performance of a procedure, but which are not in and of themselves a complete service. It is due to an oversight on our part that we did not delete these codes at that time. We stopped using C codes to describe specific devices in April 2001 and no longer create C codes to describe items of equipment. Moreover, we have found that there are existing CPT codes or, in the case of C9701, there will soon be a CPT tracking code, that will accurately report the services being furnished, and under which the hospital should report the charges for providing the services, including charges related to the equipment needed to furnish the service. Therefore, payment will be appropriate regardless of whether there are separate codes for these items of equipment.

HCPCS code C1088, the Laser Optic Treatment System, Indigo Laseroptic Treatment System, now paid under APC 0980 is no longer needed because our review of data shows that the equipment it describes is appropriately reported under CPT codes 52647 and 52648. The procedures described by these CPT codes may be performed by using several types of equipment, one of which is the type described by C1088. In fact, most of the claims containing line items for C1088 are accompanied by line items for 52647 or 52648. This means that hospitals are appropriately reporting these services under the applicable CPT codes and that any charges associated with C1088 are likely duplicate charges for the service provided. Therefore, we propose to delete C1088 and to have hospitals continue to report these services under CPT codes 52647 and 52648, which are in APC 0163.

HCPCS code C9701, the Stretta System, now paid under APC 0980, is used in a procedure that will soon be given a CPT Category Three Tracking Code by the American Medical Association's CPT Editorial Panel. We propose to use the CPT tracking code to report services using the Stretta System and to delete HCPCS code C9701. We propose to assign the new CPT tracking code in APC 1557.

HCPCS code C9703, the Bard Endoscopic Suturing System, now paid under APC 0979, is used in a procedure that has been granted a CPT Category Three Tracking Code, 0008T, which describes the procedure for which this equipment is used. We propose to delete C9703 and to require hospitals to use 0008T to report services using this equipment. We propose to assign CPT code 0008T to APC 1555 for 2004.

HCPCS code C9711, the H.E.L.P. Apheresis System, now paid under APC

0978, is used to provide apheresis, which is appropriately reported using CPT codes 36511 through 36516. Therefore, we propose to delete C9711 and to require hospitals to report the service in which this equipment is used by using CPT codes 36511 through 36516.

3. Revision of Cost Bands and Payment Amounts for New Technology APCs

In the April 7, 2000 final rule (68 FR 18477), we created 15 new technology APCs (APCs 0970 through 0984) to pay for certain new technology services under the OPPS. As discussed in both the April 7, 2000 and November 30, 2001 final rules, new technology APCs are intended to pay for new or rarely performed procedures for which we lack sufficient cost data to make an assignment to a clinical APC. New technology APCs are defined on the basis of costs, not the clinical characteristics of a service. The payment rate for each new technology APC is based on the midpoint of a range of costs.

In the November 30, 2001 final rule (66 FR 59856), we revised several of the cost bands, added a payment level to the original group of new technology APCs, and assigned status indicator ''T'' to APCs 0970 through 0985. We also created a parallel set of new technology APCs (APCs 0706 through 0721), each of which was assigned status indicator ''S.'' In addition, we changed the definition of what is appropriately paid for under a new technology APC; we refined the criteria for determining assignment of a procedure or service to a new technology APC; we clarified the information that must be supplied for a request for new technology status to be considered; and we removed the restrictions on how long a procedure can be assigned to a new technology APC. These changes, which are discussed in detail in the November 30, 2001 final rule, were implemented effective April 1, 2002.

In the November 1, 2002 final rule, we established two additional new technology APCs, APC 989, and APC 725; as these APCs were not discussed in the proposed rule, they were considered interim with comment.

In this proposed rule, we are proposing to implement a comprehensive restructuring of all the new technology APCs. First, the cost intervals in the current new technology APCs are inconsistent, ranging from $50 to $1,500. Secondly, as the number of procedures assigned to new technology APCs increases, we believe that narrower cost bands are required to avoid significant mispayment for new technology services. The increased number of new technology APCs that would result from narrowing the cost bands cannot be accommodated within the current sequence of available APC numbers. Therefore, we are proposing to dedicate two new series of APC numbers to the restructured new technology APCs, which would allow us to narrow the cost bands and also afford us flexibility in creating additional bands as future needs may dictate.

We propose to establish cost bands from $0 to $100 in increments of $50, from $100 through $2,000 in intervals of $100, and from $2,000 through $6,000 in intervals of $500. We believe that these intervals would allow us to price new technology services more appropriately and consistently. We also propose to retain two parallel sets of new technology APCs, one with status indicator ''S'' and the other with status indicator ''T.'' We invite comments on the hierarchy of cost levels of the restructured new technology APCs.

We would reassign current new technology procedures to the level in the restructured new technology APCs so that the payment amount for the procedure in 2004 closely approximates the current payment amount. As we explained in the November 30, 2001 final rule, we generally keep a procedure in the new technology APC to which it is initially assigned until we have collected data sufficient to enable us to move the procedure to a clinically appropriate APC. However, in cases where we find that our original new technology APC assignment was based on inaccurate or inadequate information, we may, based on more recent information (including claims data), reassign the procedure or service to a different new technology APC that more appropriately reflects its cost.

The proposed restructured new technology APCs are listed in Addendum A.

4. APC Assignment for New Codes Created During Calendar Year (CY) 2003

During CY 2003, we created several HCPCS codes to describe services payable under the hospital OPPS. These codes have already been assigned to APCs for CY 2003. In this proposed rule, we solicit comment on the APC assignment of these services. In addition, in this proposed rule, we propose to create a new HCPCS code with an effective date of July 1, 2003. Table 6 includes a new procedural HCPCS code created for implementation in July 2003.

Table 6 does not include new codes for drugs and devices for which we established or intend to establish pass-through payment eligibility effective July or October 2003. Furthermore, neither the new procedural HCPCS nor the new pass-through codes proposed for implementation beginning October 2003, or later, are included in Addendum B of this proposed rule.

TABLE 6—NEW G CODE FOR 2003

HCPCS code	Long descriptor	SI	Effective date	APC
G0296	PET imaging, full and partial ring PET scanner only, for restaging of previously treated thyroid cancer of follicular cell origin following negative I–131 whole body scan.	S	07/01/03	0714

5. Creation of APCs for Combinations of Device Procedures

In the course of developing the proposed rule for the 2004 OPPS, we wanted to ensure that the claims we use to set payment rates for APCs into which we package medical devices accurately reflect the costs of both the device and non-device portions of the service. As discussed in section III of this proposed rule, we have made a number of changes to our methodology for the creation of single procedure claims used to set relative weights. These changes enabled us to use charge data from more claims to set relative weights. However, we have noted that in spite of our new methodology, we were unable to significantly increase the number of single procedure claims used to set relative weights for several APCs that use high cost devices. One reason for this is that these APCs are often billed in combination with several other major procedures so that we are unable to generate single procedure claims for these APCs.

In the past, commenters have alleged that without using multiple procedure claims, we will be unable to capture the

costs of the more complex cases in which multiple procedures are performed and multiple devices are used. These commenters further requested that we change the status indicator of certain APCs from ''T'' to ''S'' in order to appropriately capture the cost of high cost devices when multiple procedures, each using devices, were billed. In addition to attempting to find a way to use multiple procedure claims, we also decided to examine our claims data to investigate whether our current payments for multiple procedures performed on the same date, each using high cost devices accurately captured the costs of the device and non-device portion of each procedure.

In order to do this, we reviewed claims from APCs that required high cost devices and from which we were unable to use the majority of claims to set a relative weight for the APC (for example, APCs for insertion of pacemakers, defibrillators, and neurostimulators). We determined the frequency with which other APCs were billed with the high cost device APCs. We then selected those claims where two APCs using high cost devices, or one APC using high cost devices and one high cost, non-device-requiring APC, were billed together with a frequency of more than 100 for the time period April 1, 2002 through September 30, 2002. This number was chosen in order to ensure that we had enough claims to determine reliable median costs. We included the APC combination 0081/0104 unintentionally and performed the analysis without realizing until after the data were developed that it had fewer than 100 claims and therefore should not have been selected. We expected that the data being used to set the 2004 weights would have a similar number of each combination to the number we found in the April 2002 to September 2002 claims. Review of Table 7, Combination APCs Used in Analysis, shows that even starting with 100 claims, we frequently had to determine median costs with very few claims. Additionally, Table 7 reveals that only a few combinations of two high cost device-requiring APCs are billed together 100 or more times. Six of the twelve combinations we analyzed (for example, claims for insertion of pacemakers and defibrillators) contained APC 0105 (Removal of pacemaker defibrillator), which is not a high cost, device-requiring APC. As the data show, APC 0105 is frequently found on multiple procedure claims, but because it is not a high cost device-requiring APC, when it is billed with these APCs, the multiple procedure reductions are applied to APC 0105. Therefore, we have determined that the vast majority of claims for APCs, such as ''insertion of Cardioverter Defibrillators,'' were not usable multiple procedure claims for the purpose of determining relative weights under our single claim process because they were billed with APC 0105.

After selecting the combinations to review, we determined the hospital costs associated with providing these ''combination'' procedures using the following methodology:

1. We selected claims where the two APCs of interest both appeared on the claim with the same date of service, and subjected them to the same trimming methodology we use for single procedure claims.
2. We then required that each APC appear on the claim only once. (For example, if two HCPCS codes from APC 0081 appeared on a claim with one HCPCS code from APC 0229, we did not use the claim. Many claims were discarded because of this requirement.)
3. From the claims in step two, we selected only those claims that included the device category codes for the devices required to perform the service. This is similar to our methodology for using single procedure claims where the procedure requires the use of a device with a category code (for example, for claims involving APCs 0222/0225, we used only claims that contained C codes for both a neurostimulator pulse generator and neuroelectrodes).
4. We ignored any line items for separately payable services under OPPS or the lab fee schedule and any line items with revenue centers containing HCPCS other than those in the APCs of interest.
5. At this point, we were left with claims where the only separately payable services were the line items for the HCPCS in the APCs of interest.
6. We packaged into the payable HCPCS codes all device category codes, all packaged HCPCS codes, and all revenue center codes without HCPCS.
7. We then determined the median cost for each APC pair using the remaining claims.

We believe the median cost estimate determined by this methodology should, if anything, overestimate the costs of the procedure combinations studied since all packaged line items were attributed to the APCs of interest unless they were clearly identified as being associated with other procedures. For example, if line items for a clinic visit and a medical or surgical supply revenue center appeared on the claim, we packaged the charges associated with the revenue center entirely into the APCs of interest and not into the APC for clinic visits.

We also determined the median costs for these APCs using our usual single claims methodology (these medians are contained in Addendum A). We then determined a summed median cost of each APC pair using our current payment policy, which allows payment at 100 percent for the most expensive APC with ''T'' status indicator and 50 percent for each additional APC with ''T'' status indicator. That is, we added the median cost of the more expensive APC and 50 percent of the median cost of the less expensive APC as a proxy for the total median cost (and payment) using our current payment policy. We then compared this figure with the median cost for the ''combination APC.'' (*See* Table 7.) We believe this comparison is an indicator of whether our current payment policy accurately pays for the costs of these APCs when they are billed together on the same date of service.

Our comparison reveals that, of the 12 ''combination APCs'' created, 7 had higher median costs than the median costs obtained with the multiple procedure methodology (we note that because APC 222 has a status indicator of ''S'', we did not apply the multiple procedure reduction for the APC 0222/0225 combination).

For three of these seven combinations, we consider the data unreliable because we were able to use very few claims to determine the ''combination'' median cost. Specifically, for APC combination 0085/0655, we were able to use only 37 claims; for APC combination 0105/0089, we were to use only 16 claims; and for APC combination 0105/0655, we were able to use only 12 claims. This is in distinction to the number of claims we used to determine the median costs for APCs 0655 and 0089 alone (1,170 and 303 respectively). Further, two of these combinations contain only one APC using high cost devices because APC 0105 does not require the use of high cost devices. This means that the multiple procedure reduction was applied to APC 0105. In such cases, we believe the reduction is appropriate because when a pacemaker or defibrillator is removed and replaced, the patient is only anesthetized once, the room only needs to be prepared once, and the time for replacement is usually less than the time for insertion due to the existence of a subcutaneous pocket.

Three other APC combinations, 0105/0090, 0105/0107, and 0105/0654, also contain only one APC requiring the use of high cost devices and therefore

should not pose the problem of underpayment due to the multiple procedure reduction, which was applied to APC 0105. Furthermore, in these three cases, the difference in median costs between the combination median and the median determined by our multiple procedure reduction methodology was, in our view, insignificant (all much less than 5 percent).

For APC combination 0222/0225, the difference in median cost could be considered significant at slightly under 5 percent, but only 74 claims were used to determine the combination median. Because we used approximately 600 claims to determine the median costs for APCs 0222 and APC 0225 individually, we consider the combination median cost comparatively unreliable.

Lastly, we note that for the other five combinations, our current payment policy pays more than the ''combination'' payment methodology.

Based on this comparison we considered several options for payment of these APCs when billed together:

1. Maintain our current payment policy.

2. Change the status indicators of certain APCs requiring the use of high cost devices to ''S.''

3. Create ''combination APCs'' with relative weights calculated using the methodology described above in order to make a single payment when the two APCs in the combination are billed together.

The third option need not result in creation of new HCPCS codes and APCs for hospitals to report. Instead, we could make changes in the logic of the outpatient code editor (OCE) so that when hospitals bill the two APCs in a combination, the OCE would ''map'' the payment to a single amount rather than paying the more expensive APC at 100 percent and the less expensive at 50 percent. The following is an example of how combination APCs might work: If a unit of a code in APC 0081 was billed with a unit of a code in APC 0104 on the same date, the multiple procedure discount would not be applied, so payment would no longer be made at 100 percent of the payment for APC 0104 (the highest paid APC in the pair) and 50 percent of the payment for APC 0081. Instead, if we were to implement combination APCs for this pair, the combination of codes would be mapped to a new ''combination'' APC, and we would make a single payment for both services. The payment rate for the new ''combination'' APC would be based upon a scaled weight calculated from the median cost for all claims containing one unit of a code from APC 0081 and one unit of a code from APC 0104 (using the methodology described above). If either of the APCs were billed without the partner APC for that established ''combination'' APC, then the APC would map to the current APC that contains the code.

Based on our analysis, we are proposing option one: Maintaining our current payment policy. We believe that our analysis shows that our current payments for these APCs adequately reflect the costs of the procedures, even when billed in combination.

We note that only a few APCs requiring the use of high cost devices are billed in combination. Thus, we do not believe there are compelling reasons to establish a new, or special, payment policy in situations where two APCs requiring high cost devices are billed together fewer than 100 times. Even when APCs are billed together, we have shown that frequently the data are unreliable due to the low number of claims we can actually use to determine the total median cost of the ''combined'' procedure. Furthermore, even where the number of usable claims is large enough to give us some assurance that the data are reliable, the median costs as determined by the two methodologies do not support any changes in our current payment policy. In some instances, adoption of the new payment policy would actually reduce payments for these services, and, in most other cases, any increase in payments would be negligible.

One commenter has brought to our attention the fact that, rarely, correct coding does not allow hospitals to bill for two APCs requiring high cost devices. One example is APC 0082 (Coronary Atherectomy) and APC 0104 (Transcoronary Stent Placement) because atherectomy is considered to be a component of stent placement when both are performed together. In those cases, we would expect hospitals to bill for all the devices used to accomplish the atherectomy and the stent placement. To the extent that both were performed, the median cost of stent placement should reflect the cost of performing an atherectomy. Therefore, we do not believe there is a compelling reason to create new payment policy for these rare situations. (See also the discussion below on ''case rate'' purchasing by hospitals.)

It could be reasoned that our analysis of the costs of ''combined'' procedures is faulty because hospital coding and billing inaccuracies may apply to these claims as well as single procedure claims (and may even be magnified). However, that reasoning would undercut, and be contrary to, the repeated comments that we need to use more multiple procedure claims to set relative weights because single procedure claims do not capture the true costs of complex procedures or episodes of care. Our investigation was performed precisely to address these concerns, determine how we might use multiple procedure claims, and what effect use of those claims would have on payment rates. Even with use of a methodology that overestimated the costs of combination procedures, we were unable to show that the median costs (and payments) using our current payment policy do not accurately reflect the costs for performing these procedures.

Other possible factors affecting our analysis include charge compression and/or inadequate charges for these procedures or the devices associated with them. However, it is not possible for us to know the magnitude of how charge compression or inadequate charges might affect costs or what methodologic or payment adjustment would be appropriate to address the problem. Furthermore, we point out that charge compression and inadequate charges should affect our cost data for these APCs when billed alone and when these APCs are billed in combination. It is unknown whether the effects would be similar in each instance but we have no reason to believe they would be different. Therefore, we do not believe that adjusting for charge compression or inadequate charges would change the ''relative'' median costs of the APCs when billed alone or in combination. Finally, we believe that the median costs of the APCs billed in combination support the concept that economies of scale are achieved in those cases. There are at least two reasons why this might occur: First, many hospitals purchase devices on a case rate or capitated basis, which means that the hospitals' device cost ''per case'' is fixed (with quarterly adjustments made based on volume and actual device use in the previous quarter(s)). For example, inserting a stent or cardioverter defibrillator requires the use of multiple devices in addition to the stent or defibrillator. A hospital may agree to pay $XXXX ''per case'' for all the devices used to insert a stent (for example, guidewires, introducers, catheters, rotablators etc.). This ''per case'' payment means that the hospital has the same cost irrespective of whether a rotablator, two catheters, or four catheters were used for a specific patient. Second, even if hospitals purchase devices on a ''per device'' basis, it is possible that no extra catheters, guidewires, and/or

introducers, for example, are used when a second related procedure is performed (for example, an electrophysiology study and a defibrillator lead placement, or an angioplasty and a stent placement).

In summary, we have concluded that there is no compelling reason to change our current payment policy for APCs requiring the use of high cost devices.

We solicit public comments on our methodology, analysis, and payment options for these APCs. We particularly solicit comments on how our analysis should affect any use of external data sources in the final rule. Specifically, we ask commenters to explain why submitted external data should be used in preference to our single or multiple claim data for APCs requiring the use of high cost devices.

We also note that creation of ''combination APCs'' would allow us to set relative weights using a number of claims that we otherwise would not be able to use. Therefore we solicit comments on this approach to using more claims to set relative weights and specifically request comments on how to use those claims even if we do not create ''combination APCs.''

TABLE 7.—COMBINATION APCS USED IN ANALYSIS

Combination of APCs	Descriptions of both APCs in the combination	Sum of single APC medians adjusted for multiple procedure policy	Frequency of combination APC billed on the same date	Frequency of claims used for median cost of services in both APCs	Median cost of services in both APCs	Percent difference median for both APCs to sum of adjusted single medians
0081/0104	Noncoronary Angioplasty/Athectomy & Transcatheter Placement of Intracoronary Stent.	$5,760.50	55	2	$5,589.14	−2.97
0081/0229	Noncoronary Angioplasty/Athectomy & Transcatheter Placement of Iintravascular Stent.	4,507.09	6177	135	4,116.50	−8.67
0085/0108	Level II Electrophysiologic Evaluation & Insertion/Replacement/Convert of Cardioverter Defibrillator.	29,749.68	502	63	20,438.99	−31.30
0085/0655	Level II Electrophysiologic Evaluation & Insertion/Replacement/Conversion of Permanent Dual Chamber Pacemaker.	9,398.45	268	37	10,832.16	15.25
0105/0089	Revision/Removal of Pacemakers, AICD, or Vascular & Insertion/replacement of Permanent Pacemaker and Electrodes.	7,360.80	221	16	12,268.96	66.68
0105/0090	Revision/Removal of Pacemakers, AICD, or Vascular & Insertion/replacement of Permanent Pacemaker Pulse Generator.	5,668.72	1426	516	5,751.30	1.46
0105/0107	Revision/Removal of Pacemakers, AICD, or Vascular & Insertion of Cardioverter-Defibrillator.	17,579.21	1106	235	18,294.85	4.07
0105/0108	Revision/Removal of Pacemakers, AICD, or Vascular & Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads.	29,239.29	294	8	26,843.72	−8.19
0105/0654	Revision/Removal of Pacemakers, AICD, or Vascular & Insertion/Replacement of a permanent dual chamber pacemaker.	6,639.65	3653	1475	7,014.00	5.64
0105/0655	Revision/Removal of Pacemakers, AICD, or Vascular & Insertion/Replacement/Conversion of a Permanent Dual Chamber Pacemaker.	8,888.06	237	12	10,290.88	15.78
0222/0225	Implantation of Neurological Device & Implantation of Neurostimulator Electrodes.	14,345.41	368	74	15,002.40	4.58
0223/0227	Implantation of Pain Management Device & Implantation of Drug Infusion Device.	10,350.16	222	65	9,815.08	−5.17

Table 7 lists the combinations that we investigated, abbreviated titles for the single APCs in the pair, the number of times the APCs were billed together, the number of claims used to set the combination APC median, a combined median cost for claims in which both the APCs appeared (derived from the methodology discussed above), the median cost for the two APCs using the multiple procedure reduction policy, and the difference in median costs (expressed in percent).

6. New APC for Antepartum Care

We propose to split APC 0199, Obstetrical Care Service into two APCs. New APC 0700, Antepartum Care Service, would be created and 59412 (external cephalic version) would be assigned there. The two remaining HCPCS code 59409 (vaginal delivery only) and 59612 (vaginal delivery only, after previous cesarean delivery) would remain in APC 0199, Obstetrical Care Service. We propose to make this change because of the great difference in cost between vaginal delivery and the external cephalic version procedures. We believe that inclusion of the lower cost procedure in the APC with vaginal deliveries may have an affect on the median cost for the APC that results in less accurate payment.

III. Recalibration of APC Weights for CY 2004

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 2001. 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 to 67827).)

To recalibrate the relative APC weights for services furnished on or after January 1, 2004 and before January 1, 2005, 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 propose 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 2004, the most recent available claims data are the approximately 115 million final action claims for hospital outpatient department services furnished on or after January 1, 2002 and before January 1, 2003. We then eliminated the following 45.7 million claims because many of these claims were for services that are not paid under OPPS: Claims in the first quarter of calendar year 2002; claims for bill types other than OPPS bill types; claims for services furnished in Maryland, Guam, and the Virgin Islands. We matched the 69.3 million claims that were paid under the OPPS to the most recent cost report filed by the individual hospitals represented in our claims data. The APC relative weights would continue to be based on the median hospital costs for services in the APC groups.

A. Data Issues

1. Period of Claims Data Used

We propose to use claims for the period beginning April 1, 2002 through and including December 31, 2002 as the base for the CY 2004 OPPS. The statute requires that we take into account new cost data and other relevant information and factors in reviewing and revising the weights, and we believe that this period will give us the most recent costs. We chose not to include the claims for the period beginning on January 1, 2002 through March 31, 2002 because they were used to set the payment rates for the 2003 OPPS and we believe that the most recent 9 months of claims data will result in payment rates that are most representative of the current relative costs of hospital outpatient services.

The claims base used to calculate the proposed payment weights and payment rates in this proposed rule is not the totality of claims on which the final weights and rates will be based. The use of this claims base is due to (1) a lag in claims submission by providers; (2) a statutory limit on the date before which no claim can be paid; and (3) the additional processing time it takes for the claims data to be included in the national claims history, which is the source of our claims data. For these reasons, the claims data used for this proposed rule are for the period of services furnished between April 1, 2002 and November 1, 2002. However, when the final weights and rates are calculated, we will have access to approximately 95 percent of the claims data for services furnished from April 1, 2002 through December 1, 2002.

2. Treatment of ''Multiple Procedure'' Claims

We have received many requests asking 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 2004 relative payment weights. Those making the requests 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.

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. We identified certain multiple-procedure claims that could be treated as single-procedure claims, enabling us to greatly increase the number of services used to develop the APC payment weights for CY 2003. However, several inherent features of multiple procedure claims prevented us from using all of them to recalibrate the payment weights. We discussed these obstacles in detail in the August 9, 2002 proposed rule (67 FR 52092, 52108 through 52111), and the November 1, 2002 final rule (67 FR 66718, 66743 through 66746).

For the CY 2004 OPPS, we propose several changes to how we handle and use claims data to enable us to use more claims in the creation of median costs on which our payment weights and rates are based. Specifically, we propose to expand the number of HCPCS codes that we ignore for purposes of creating a pseudo single claim from claims that contain other separately payable HCPCS codes. We also looked at dates of service on packaged HCPCS codes and packaged revenue centers, and propose, where possible, to attribute the charges to major, separately payable HCPCS codes based on the codes' dates of service. Our complete discussion of the use of data to set the weights for CY 2004 OPPS follows in section III.B of this proposed rule.

Expansion of the list of codes to be ignored in creation of single claims. For CY 2003 OPPS, we ignored the presence of HCPCS codes 93005, 71010, and 71020 to create pseudo single claims where there was one remaining separately paid, major HCPCS code on the claim. This enabled us to attribute the costs of packaged HCPCS codes and packaged revenue centers to the remaining separately paid HCPCS codes and, therefore, to use the charge data on the claim. We did this based on our belief that these three separately payable HCPCS codes would not have charges related to them that would be placed in packaged HCPCS codes or packaged revenue centers. Instead, we believe that the charges found in the packaged HCPCS or packaged revenue centers would be appropriately associated with the only other separately payable HCPCS that remained on the claim when these codes are ignored.

For CY 2004 OPPS, we propose to expand the list of HCPCS codes that we would ignore for purposes of creating pseudo single claims. On claims that contain other separately payable HCPCS, we propose to ignore the HCPCS codes in the APCs identified in Table 9. As with HCPCS codes 93005, 71010, and 71020, we believe that these codes are highly unlikely to have charges that are found in packaged HCPCS or in packaged revenue centers. Therefore, we believe that they can be ignored for the purpose of creating a pseudo single claim from the remaining charges on the claim. We solicit comments on the proposed methodology to create pseudo single claims, on the list of codes in Table 9 that we propose to ignore, and whether there are other low cost services that we could ignore in using this methodology. We also request comments on whether we should use the charges for the codes in the APCs in Table 9 to create pseudo single claims to be used in setting the median costs for these APCs.

Use of dates of service to create single claims. For CY 2003, we did not use dates of service to attribute charges on packaged HCPCS and packaged revenue centers to major separately payable HCPCS codes. For CY 2004, we propose to use dates of service on HCPCS codes and on packaged revenue centers to attribute charges to a major payable HCPCS code where the dates of service match. We can only use this approach where there are different dates of service for the separately payable major HCPCS codes. Where there are multiple major payable HCPCS codes on a claim with the same date, we cannot use this approach because there is no way to tell to which major payable HCPCS code the charges from the packaged HCPCS or packaged revenue center belong. Moreover, where the hospital does not provide dates for all packaged revenue centers, we cannot attribute charges based on the date of service.

We believe that this methodology yields more single claims than if we did not use dates of service. However,

because hospitals are not required to put dates of service for line items with only a revenue center but no HCPCS code, we will not be able to perform this analysis routinely for each claim. Therefore, the claims from hospitals that do provide those dates are more likely to be used for weight-setting than claims of hospitals that do not provide those dates on the claim. We are unable to determine what impact, if any, this methodology has on the weights for the services and we solicit comments on the approach.

We invite comments on whether we should require hospitals to enter a line item date of service for every OPPS charge. We are interested in receiving comments regarding the implications the policy would have for hospitals, including potential obstacles and estimates on the amount of time that would be required to implement this change.

3. Adjustment of Median Costs for CY 2003 OPPS

The relative weights of several APCs, especially APCs requiring the use of high cost devices, that were developed for the 2003 OPPS fee schedule, using claims data from April 1, 2001 to March 31, 2002, showed a significant decrease from the relative weights that were established for the 2002 OPPS fee schedule. The 2002 OPPS relative weights were based on both claims data and packaging of 75 percent of the manufacturer submitted costs for devices into the APC cost. Using our April 1, 2001, through March 31, 2002 claims data resulted in significant decreases in payment for many blood products and separately payable drugs. In order to minimize any beneficiary access problems related to the reduction in payment for blood products, separately payable drugs, and certain device-related APCs, we created a limit for any payment reductions as follows:

Device and Procedural APCs

For APCs requiring the use of one or more devices receiving pass-through payments, we determined the median cost of the APC using only claims that contained device category ''C'' codes. For selected APCs, we used only claims containing the device ''C'' code specific to the service furnished (for example, we used only claims containing the ''C'' codes for cardioverter defibrillators to determine the median cost for the APC for inserting cardioverter defibrillators).

We then compared the median costs established for the 2002 OPPS fee schedule and the median costs based on our April 1, 2001, through March 31, 2002 claims data and limited decreases in median costs (from the 2002 fee schedule) by 15 percent plus half the amount of any reduction beyond 15 percent (for example, if the claims data showed the median cost of an APC decreased 45 percent, the amount of allowed reduction would have been 15 percent + ½ × (45 percent − 15 percent) = 30 percent). For a few APCs where device costs accounted for more than 80 percent of the total cost of the APC, we also incorporated external data into our calculation of the median cost.

Blood and Blood Products

We limited reductions in median costs to 11 percent as compared to the 2002 median costs so that the reduction in payments, after other adjustments, for these items would generally not exceed 15 percent.

Separately Payable Drugs

We noted in the November 1, 2002 final rule that the reason our April 1, 2001, through March 31, 2002 claims data resulted in lower median costs for many drugs was that the payment rates for 2002 were based on 95 percent of average wholesale price (AWP) as required by law for pass-through drugs. We believed, and continue to believe, that the acquisition cost for many drugs is considerably less than 95 percent of AWP. However, we limited reductions in median costs for separately payable drugs and for administration of packaged drugs using the same methodology as described above for device and procedural APCs.

Procedural and Device Intense APCs for 2004 OPPS

Comparison of procedural APC medians for 2004 OPPS to adjusted medians for 2003 OPPS. Our analysis of the April 1, 2002, through December 31, 2002 claims data, which is the basis for the proposed median costs for the 2004 OPPS, reveals a distribution of changes in median costs that are not unusual. Compared to the adjusted median costs used for the 2003 OPPS, most of the median cost increases and decreases were for nondevice-related APCs. Very few device-related APCs saw their median costs decrease significantly. We also note that, with a few exceptions, the median cost increases and decreases were not unusually distributed; we believe that the fluctuations should not be unexpected in a new payment system. For example, the cost of providing items and services changes yearly and, in a new payment system, the accuracy of coding services will improve year to year. We also compared the actual median costs from the April 1, 2001 through March 31, 2002 claims data with the actual median costs from the April 1, 2002 through December 31, 2002 claims data. Given the level of consistency we see in our claims data, we believe that adjustment of median costs last year may have resulted in payment amounts for some APCs that were too high.

The medians we propose to use to set weights for the 2004 OPPS for APCs in Table 8 have decreased more than 10 percent in median cost when compared to the adjusted median costs for 2003 OPPS. For reference, we also provide the actual median cost from the claims data we used to set 2003 OPPS payment rates. Some changes appear to be the result of normal fluctuation in the costs of services. In other cases the actual median cost in the April through December 2002 data (the 2004 OPPS medians) is consistent with the actual median cost in the April 1, 2001 through March 31, 2002 data (used for the 2003 OPPS medians), but decreased significantly only in comparison to the adjusted 2001 medians used for 2003 OPPS. In general, where there is consistency between the 2001 (2003 OPPS) and 2002 (2004 OPPS) unadjusted medians or where a change appears to represent normal fluctuations in costs, and we know of no special circumstances that would cause us to believe that there are problems in the claims data, we conclude that the claims data accurately represent the cost of the service. After reviewing the data, we believe that there is no sound basis for making an across-the-board adjustment to our April through December 2002 median costs, notwithstanding that using the unadjusted 2004 median may result in a reduced payment compared to the payment that was based on adjusted medians under 2003 OPPS.

TABLE 8.—APCS WITH MEDIAN COST DECREASES OF 10 PERCENT OR MORE

Final APC	Description	SI	Final 2003 dampened median cost	2004 proposed rule APC median cost	% diff APC median cost (2003 dampened vs. 2004 proposed rule)
0312	Radioelement Applications	S	$3,141.77	$216.18	−93.12
0330	Dental Procedures	S	284.02	32.87	−88.43
0692	Electronic Analysis of Neurostimulator Pulse Generators	S	371.55	56.40	−84.82
0651	Complex Interstitial Radiation Source Application	S	3,250.63	588.67	−81.89
0225	Implantation of Neurostimulator Electrodes	S	8,277.07	3,283.68	−60.33
0352	Level I Injections	X	13.10	6.31	−51.83
0068	CPAP Initiation	S	123.29	65.83	−46.61
0124	Revision of Implanted Infusion Pump	T	2,975.12	1,608.78	−45.93
0688	Revision/Removal of Neurostimulator Pulse Generator Receiver	T	4,429.71	2,495.57	−43.66
1719	Brachytx seed, Non-HDR Ir–192	K	31.04	17.89	−42.36
0699	Level IV Eye Tests & Treatments	T	223.07	130.15	−41.65
0199	Obstetrical Care Service	T	232.46	142.74	−38.59
0313	Brachytherapy	S	1,249.57	769.14	−38.45
0236	Level II Posterior Segment Eye Procedures	T	1,873.66	1,153.59	−38.43
0123	Bone Marrow Harvesting and Bone Marrow/Stem Cell Transplant	S	380.54	234.84	−38.29
0223	Implantation or Revision of Pain Management Catheter	T	2,437.21	1,525.61	−37.40
0385	Level I Prosthetic Urological Procedures	T	6,199.09	3,895.76	−37.16
0681	Knee Arthroplasty	T	8,780.47	5,669.25	−35.43
0302	Level III Radiation Therapy	S	548.35	363.26	−33.75
0301	Level II Radiation Therapy	S	187.53	125.03	−33.33
0094	Level I Resuscitation and Cardioversion	S	228.18	154.77	−32.17
0671	Level II Echocardiogram Except Transesophageal	S	140.57	96.05	−31.67
0098	Injection of Sclerosing Solution	T	99.06	68.15	−31.20
0346	Level II Transfusion Laboratory Procedures	X	30.59	22.72	−25.73
0043	Closed Treatment Fracture Finger/Toe/Trunk	T	148.63	112.70	−24.17
0687	Revision/Removal of Neurostimulator Electrodes	T	1,535.37	1,171.45	−23.70
0359	Level II Injections	X	67.50	51.53	−23.66
0122	Level II Tube changes and Repositioning	T	638.40	494.56	−22.53
0363	Level I Otorhinolaryngologic Function Tests	X	64.56	50.02	−22.52
0081	Non-Coronary Angioplasty or Atherectomy	T	2,584.47	2,041.29	−21.02
0191	Level I Female Reproductive Proc	T	12.27	9.84	−19.80
0685	Level III Needle Biopsy/Aspiration Except Bone Marrow	T	355.90	286.61	−19.47
0371	Level I Allergy Injections	X	29.69	23.93	−19.39
0152	Percutaneous Abdominal and Biliary Procedures	T	595.64	486.01	−18.41
0222	Implantation of Neurological Device	T	13,528.13	11,061.74	−18.23
0118	Chemotherapy Administration by Both Infusion and Other Technique	S	325.75	267.63	−17.84
0086	Ablate Heart Dysrhythm Focus	T	3,138.30	2,611.43	−16.79
0202	Level VIII Female Reproductive Proc	T	2,706.38	2,273.91	−15.98
0228	Creation of Lumbar Subarachnoid Shunt	T	3,541.71	2,996.28	−15.40
0347	Level III Transfusion Laboratory Procedures	X	66.49	56.52	−14.99
0245	Level I Cataract Procedures without IOL Insert	T	863.71	736.87	−14.69
0189	Level III Female Reproductive Proc	T	90.69	77.39	−14.67
0085	Level II Electrophysiologic Evaluation	T	2,478.31	2,128.77	−14.10
0665	Bone Density: AppendicularSkeleton	S	49.02	42.34	−13.63
0670	Intravenous and Intracardiac Ultrasound	S	1,796.55	1,555.61	−13.41
0368	Level II Pulmonary Tests	X	62.61	54.62	−12.76
0107	Insertion of Cardioverter-Defibrillator	T	19,378.60	17,025.21	−12.14
0362	Level III Otorhinolaryngologic Function Tests	X	168.41	148.74	−11.68
0287	Complex Venography	S	415.06	368.16	−11.30
0120	Infusion Therapy Except Chemotherapy	T	129.56	115.11	−11.15
0212	Nervous System Injections	T	196.63	175.73	−10.63
0004	Level I Needle Biopsy/ Aspiration Except Bone Marrow	T	103.36	92.43	−10.57
0676	Level II Transcatheter Thrombolysis	T	245.24	219.77	−10.39
0268	Ultrasound Guidance Procedures	S	82.47	74.07	−10.19
0106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	T	3,256.61	2,927.17	−10.12

We solicit comments on the proposed weights for all APCs and for the APC placement of all HCPCS codes. However, because we believe the public may be interested in commenting on APCs where the payment rate decreases, we discuss several APCs whose payment rates decrease by more than 10 percent. We are particularly interested in comments, including the submission of external data (as discussed below) regarding these APCs.

Discussion of Selected APCs

APC 312 Radioelement Applications—The proposed median for this APC falls 93.12 percent in comparison with the 2003 adjusted median (from $3,141.77 to $216.18). The 2003 OPPS median was adjusted against

the 2002 OPPS median ($7,080.00) into which we packaged the cost of brachytherapy seeds. However, for 2003 and 2004, we are making separate payment for bracytherapy seeds (with the exception of prostate brachytherapy) and, therefore, the costs of those seeds is not packaged into the APC payment (except for prostate brachytherapy). The 2003 OPPS unadjusted median was $265.53, which is comparable to the proposed 2004 OPPS median. Hence, we think the 2003 OPPS median reflects the costs of brachytherapy, with seeds paid separately.

APC 692 Electronic Analysis of Neurostimulator Pulse Generators—The proposed median for this APC falls 84.82 percent in comparison with the 2003 OPPS adjusted median (from $371.55 to $56.40). The 2003 OPPS median was adjusted against the 2002 OPPS median ($819.00), which contained costs for devices that should not have been packaged. Moreover, the 2003 OPPS unadjusted median for the service was $46.95, and this is comparable to the 2004 OPPS median of $56.40. Hence, we believe that the proposed 2004 OPPS median reflects the cost of the service.

APC 651 Complex Interstitial Radiation Source Application—The proposed median for this APC falls 81.89 percent in comparison with the 2003 OPPS adjusted median (from $3,250.63 to $588.67). The 2003 OPPS median was adjusted against the 2002 OPPS median ($7,080.00), which contained costs for brachytherapy seeds that are currently paid separately. Moreover, the 2003 OPPS unadjusted median for the service was $483.25, and this is comparable to the proposed 2004 OPPS median of $588.67. Hence, we believe that the proposed 2004 OPPS median reflects the cost of the service because brachytherapy seeds are paid separately.

APC 225 Implantation of Neurostimulator Electrodes—The proposed median for this APC fell 60.33 percent (from $8,277.07 to $3,283.68) as compared to the adjusted median used for the 2003 OPPS. The 2003 OPPS median was adjusted against the 2002 OPPS median ($15,286.00), which reflected the manufacturer(s) price(s) for the devices packaged into the APC. However, the proposed 2004 OPPS median ($3,283.68) is very close to the unadjusted 2003 OPPS median ($3,561.03), causing us to believe that the 2004 proposed median accurately reflects the costs of the procedure. Because this APC is commonly performed with implantation of a neurostimulator pulse generator (APC 222), we changed the status indicator of APC 225 to ''S'' so that it would not be subjected to the multiple procedure reduction when it is performed with implantation of a neurological device. We do not propose to change the status indicator this year, and the multiple procedure reductions would not be applied in CY 2004 to APC 0225.

We determined the proposed 2004 OPPS median for APC 225, using only claims that contained the C codes for the neurostimulator leads (either C1778 Lead, neurostimulator, or C1897 Lead, neurostimulator test kit) in order to ensure that we captured the costs for the leads in the data used to calculate the median. We solicit comments concerning the accuracy of our data and whether they appropriately reflect the cost of neurostimulator electrodes, as well as submission of data on the acquisition cost of neurostimulator electrodes (both permanent and test electrodes).

APC 352 Level 1 Injections—The proposed 2004 OPPS median for this APC fell 51.83 percent (from $13.10 to $6.31) as compared to the adjusted 2003 OPPS median. The 2003 OPPS median was adjusted against the 2002 OPPS median ($23.00). However, the 2003 OPPS median ($6.65) is very close to the proposed 2004 OPPS median ($6.31), and this leads us to believe that the proposed 2004 median reflects the cost of the service.

APC 313 Brachytherapy.—The proposed median for this APC falls 38.45 percent in comparison with the 2003 OPPS adjusted median (from $1,249.57 to $769.14) because the 2003 OPPS median was adjusted against the 2002 OPPS median ($2,030.00), which contained costs for brachytherapy seeds that should not have been included because the radioelement sources used in this APC are not single use seeds. Moreover, the 2003 OPPS unadjusted median for the service was $773.63, and this is comparable to the proposed 2004 OPPS median of $769.14. Hence, we believe that the proposed 2004 OPPS median reflects the cost of the service.

APC 223 Implantation or Revision of Pain Management Catheter.—The proposed median for this APC falls 37.40 percent in comparison with the 2003 OPPS adjusted median (from $2,437.21 to $1,525.61). The single CPT code in this APC describes three procedures: revision, repositioning, and insertion of a pain management catheter. Therefore, the median cost of this APC should reflect the relative frequencies with which these three procedures are performed. Furthermore, the descriptor makes it inappropriate to use only claims containing ''C'' codes to determine the median cost for this APC because a device is not always used when this procedure is performed. To require that a ''C'' code be on claims for this procedure would result in inaccurate median costs. We believe the decrease in median cost is due to the packaging of 75 percent of the cost of the catheter into the APC amount for the 2002 OPPS fee schedule.

APC 385 Level 1 Prosthetic Urological Procedures.—The proposed median for this APC fell 37.16 percent compared to the adjusted median for this APC in 2003 OPPS ($3895.76 compared to $6,199.09). This occurred because we removed the more expensive inflatable penile prosthesis and prosthetic urinary sphincters from APC 179 and placed them in a new APC (APC 386 with proposed 2004 OPPS median of $6,298.89). Hence, we believe that the proposed medians for both APCs reflect the costs of the services that they now contain.

APC 687 Revision/Removal of Neurostimulator Electrodes—The proposed median costs of this APC decreased 23.7 percent as compared to the adjusted median used for the 2003 OPPS fee schedule ($1,171.45 compared to $1,535.37). (*See* Table 8.) However, none of the procedures in this APC require the use of high cost devices, and we believe the change in median cost reflects fluctuation in the costs of providing these services.

APC 359 Level II Injections—*See* section VI.B.4 of this proposed rule for the discussion of administration of drugs.

APC 81 Non Coronary Angioplasty or Atherectomy—The median for this APC fell 21.02 percent in comparison with the actual median cost used in the 2003 OPPS fee schedule (from $2,584.47 to $2,041.29). The median cost used for OPPS 2003 was significantly higher than the median cost used for the 2002 OPPS, which included packaging of 75 percent of the devices used in this APC. We believe the decrease this year, which is still substantially higher than the median used for 2002, reflects the fluctuating costs of providing this service.

APC 222 Implantation of Neurological Device—The proposed median for this APC fell 18.23 percent in comparison with the 2003 OPPS adjusted median (from $13,528.13 to $11.528.13). The 2003 OPPS adjusted median was adjusted against the 2002 OPPS median, which packaged 75 percent of the cost (based on manufacturer submitted data) of the devices ($17,284.00) into the APC. However, the proposed 2004 OPPS median of $11,061.74 compares favorably with the unadjusted 2003 OPPS median of $9,146.22. Because we

developed the proposed 2004 median for APC 222 using only claims that contained charges for device code C1767, we believe our current cost data better reflect the cost of these devices. We solicit comments on the accuracy of our data as well as the submission of data on the acquisition cost of these devices.

APC 118 Chemotherapy Administration by Both Infusion and Other Technique—See section VI.B.4 of this proposed rule for the discussion of administration of drugs.

APC 86 Ablate Heart Dysrhythm Focus—The proposed median for this APC fell 16.79 percent for 2004 OPPS when compared to the adjusted median for 2003 (from $3,138.30 to $2,611.43). The proposed 2004 OPPS median is comparable to the unadjusted median for 2003 OPPS of $2,745.69. Because this APC requires the use of a device, we required that the claims used to set the median for this APC contain a device code to qualify. We believe that our cost data accurately reflect the cost of providing this service. We note that the high payment rate for 2003 was adjusted against the 2002 median, which reflected packaging 75 percent of the device cost (based on manufacturer submitted costs) into the APC.

APC 202 Level VIII Female Reproductive Procedure—We made several changes to the structure of this APC and the proposed median for this APC fell 15.98 percent for 2004 OPPS when compared to the adjusted median for the 2003 (from $2,706.38 to $2,273.91). The proposed 2004 OPPS median is comparable to the unadjusted median for 2003 OPPS of $2,327.25. This APC requires the use of a device and, therefore, we required that the claims used to set the median for this APC must contain one or more specified device codes to qualify (C1771 Repair device, urinary incontinence, with sling graft, C2631 Repair device, urinary incontinence, without sling graft). We believe our cost data accurately reflect the costs of providing this service.

APC 670 Intravenous and Intracardiac Ultrasound—The proposed median for this APC fell 13.41 percent for the 2004 OPPS when compared to the median for 2003 OPPS (from $1,796.55 to $1,555.61). This APC requires the use of a device and therefore we required that the claims used to set the median for this APC must contain a device code to qualify. We believe that our cost data accurately reflect the cost of providing this service and that any change in median cost is due to fluctuations in hospital costs.

APC 107 Insertion of Cardioverter-Defibrillator—The proposed 2004 OPPS median for this APC fell 12.14 percent (from $19,378.60 to $17,025.21) as compared to the adjusted median cost for the 2003 OPPS fee schedule. The 2003 OPPS median was adjusted against the 2002 OPPS median ($21,679.00) which reflected packaging 75 percent of the manufacturer submitted prices for the devices used in this APC. The proposed 2004 OPPS median is much closer to the adjusted median than it is to the unadjusted 2003 OPPS median ($13,572.62).

We acquired the proposed 2004 OPPS median for APC 107 by using only claims that contained the C codes for cardioverter-defibrillators (either C1721 Cardioverter-defibrillator dual chamber, C1722 Cardioverter-defibrillator, single chamber, or C1882 Cardioverter-defibrillator, other than single or dual chamber) in order to ensure that we captured the costs for the device in the data used to calculate the median. Although the proposed median cost of this APC is lower than the adjusted median used last year, it is considerably higher than the actual median from last year, and we have confidence that it reflects the cost of the devices used in the procedure. We would also note that the proposed median cost for APC 108 also rose dramatically and is higher than the adjusted median used for the 2003 OPPS fee schedule. Assuming that the proposed median cost for APC 108 accurately reflects the cost of inserting a cardioverter-defibrillator with leads, we would expect that the proposed median cost of APC 107, which also rose significantly as compared to the actual median cost used for OPPS 2003, accurately reflects the cost of inserting a cardioverter-defibrillator without leads.

APC 120 Infusion Therapy Except Chemotherapy—See section VI.B.4 of this proposed rule for a discussion of infusion therapy other than chemotherapy.

APC 106 Insertion/Replacement/Repair of Pacemaker and/or Electrodes—The proposed 2004 OPPS median for this APC fell 10.12 percent compared to the 2003 OPPS median (from a final 2003 OPPS median of $3,256.61 to a proposed 2004 Median of $2,927.17). This APC contains both CPT codes for insertion of temporary pacemaker leads (CPT codes 33210 and 33211) and repair and revision of pacemaker leads (33216, 33217, 33218, and 33220). This APC contains a mixture of services and, therefore, its median cost should reflect the mixture of services provided. We solicit comments on whether the proposed median cost for this APC reflects the cost of providing these services as well as the submission of data on the acquisition costs of the leads used for each service in this APC.

Preferred Characteristics of External Data Submitted in Comments. We will consider external data on devices that are provided to the extent that they enable us to verify or adjust claims data where we are convinced that an adjustment is appropriate. All data we use to create payment amounts for the final rule will be available for public inspection.

External data must meet the following criterion:

- Be available for public inspection.

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, urban) and by type (for example, community, 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, by quarter for the last 3 quarters of 2002. Cost data for 2003 are not compatible with 2002 claims data.

This information would enable us to compare our claims data to the external data and help us determine whether the submitted data are representative of hospitals that submit claims under OPPS.

Please note that information that contains beneficiary-specific information (for example, medical records, invoices with beneficiary identification on it) should 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, Medicare or other insurance number, etc. Moreover, individually identifiable beneficiary medical records, including progress notes, medical orders, test results, consultation reports, etc. should

not be submitted to us. Similarly, photocopies of checks from hospitals or other documents that contain bank routing numbers should not be submitted to us.

Blood and Blood Products

See section VI.B.8 of this proposed rule for our discussion of the analysis of data for blood and blood products and our proposal.

Separately Paid Drugs

See section VI.B.3 of this proposed rule for our discussion of the analysis of data for separately paid drugs and our proposal.

B. Description of How We Propose To Calculate Weights for CY 2004

The methodology we followed to calculate the APC relative payment weights proposed for CY 2004 is as follows:

- We excluded from the data claims for those bill and claim types that would not be paid under the OPPS (for example, bill type 72X for dialysis services for patients with end-stage renal disease (ESRD)).
- We eliminated claims from hospitals located in Maryland, Guam, and the U.S. Virgin Islands.
- Using the most recent available cost report from each hospital, we converted billed charges to costs and aggregated them to the procedure or visit level first by identifying the cost-to-charge ratio specific to each hospital's cost centers (''cost center specific cost-to-charge ratios'' or CCRs) and then by matching the CCRs to revenue centers used on the hospital's CY 2001 outpatient bills. The CCRs include operating and capital costs but exclude items paid on a reasonable cost basis.
- We eliminated from the hospital CCR data 325 hospitals that we identified as having reported charges on their cost reports that were not actual charges (for example, a uniform charge applied to all services). Of these, only 166 hospitals had claims data.
- We eliminated from our data claims for critical access hospitals that are not paid under OPPS and whose claims are therefore not suitable for use in setting weights for services paid under OPPS.
- We calculated the geometric mean of the total operating CCRs of hospitals remaining in the CCR data. We removed from the CCR data 29 hospitals whose total operating CCR deviated from the geometric mean by more than three standard deviations.
- We excluded from our data approximately 2.1 million claims submitted by the hospitals that we removed or trimmed from the hospital CCR data.
- We matched revenue centers from the remaining universe of claims to hospital CCRs.
- We separated the 66.345 million claims that we had matched with a cost report into the following three distinct groups: (1) Single-procedure claims; (2) multiple-procedure claims; and (3) claims on which we could not identify at least one OPPS covered service. Single-procedure claims are those that include only one HCPCS code (other than laboratory and incidentals such as packaged drugs and venipuncture) that could be grouped to an APC. Multiple-procedure claims include more than one HCPCS code that could be mapped to an APC. Thus, dividing the claims yielded approximately 21.92 million single-procedure claims and 14.8 million multiple-procedure claims. Approximately 19.57 million claims without at least one covered OPPS service were set aside.

We converted 8.47 million multiple-procedure claims to single-procedure claims using the following criteria: (1) If a multiple-procedure claim contained lines with a HCPCS code in the pathology series (that is, CPT 80000 series of codes), we treated each of those lines as a single claim. (2) For multiple-procedure claims with a packaged HCPCS code (status indicator ''N'') on the claim, we ignored line items for preoperative procedures and for those services in the APCs identified in Table 9. These are services with payment amounts below $50 (under CY 2003 OPPS) for which we believe the charge represents the totality of the charges associated with the service (that is, that there are no packaged HCPCS or packaged revenue centers attributable to the service). If only one procedure (other than HCPCS codes in Table 9) existed on the claim, we treated it as a single-procedure claim. (3) If the claim had no packaged HCPCS codes and if there were no packaged revenue centers on the claim, we treated each line with a procedure as a single-procedure claim if billed with single units. (4) If the claim had no packaged HCPCS codes but had packaged revenue centers for the procedure, we ignored the line item for codes in the APCs identified in Table 9. If only one HCPCS code remained, we treated the claim as a single-procedure claim.

TABLE 9.—APCS THAT WERE IGNORED TO CREATE PSEUDO SINGLE PROCEDURE CLAIMS

0001	Level I Photochemotherapy	S
0060	Manipulation Therapy	S
0077	Level I Pulmonary Treatment	S
0099	Electrocardiograms	S
0215	Level I Nerve and Muscle Tests	S
0215	Level I Nerve and Muscle Tests	S
0230	Level I Eye Tests & Treatments	S
0260	Level I Plain Film Except Teeth	X
0262	Plain Film of Teeth	X
0271	Mammography	S
0341	Skin Tests and Miscellaneous Red Blood Cell Tests	X
0342	Level I Pathology	X
0343	Level II Pathology	X
0344	Level III Pathology	X
0345	Level I Transfusion Laboratory Procedures	X
0364	Level I Audiometry	X
0367	Level I Pulmonary Test	X
0669	Digital Mammography	S
0690	Electronic Analysis of Pacemakers and other Cardiac Devices	S
0706	New Technology—Level I ($0–$50)	S

In addition, we assessed the dates of service for HCPCS codes and packaged revenue centers on each claim that contained more than one major code. Where it was possible to attribute charges for packaged HCPCS and packaged revenue centers to HCPCS codes for major procedures by matching unique dates of service, we did this and created single claims by packaging charges into the charge for the major service on the same date. We were only able to do this if the multiple major procedures had different dates of service and if there were dates of service on all of the packaged revenue centers. Dates of service on revenue centers are not required and, therefore, only claims from hospitals that submitted dates of service on revenue centers in CY 2002 could be used in this process for maximizing the number of single-procedure claims to be used for weight setting. We created an additional 23.58 million single-procedure bills through this process, which enabled us to use these data from multiple-procedure claims in calculation of the APC relative payment weights.

• To calculate median costs for services within an APC, we used only single-procedure bills and those multiple-procedure bills that we converted into single claims except as described otherwise. If a claim had a single code with a zero charge (that would have been considered a single-procedure claim), we did not use it. As we discussed in section III.A.2 of this proposed rule, we did not use multiple-procedure claims that billed more than one separately payable HCPCS code with charges for packaged items and services such as anesthesia, recovery room, or supplies that could not be reliably allocated or apportioned among the primary HCPCS codes on the claim. We have not yet developed what we regard as an acceptable method of using multiple procedure bills to recalibrate APC weights that minimizes the risk of improperly assigning charges to the wrong procedure or visit.

For APCs in Table 10, we required that there be a C code on the claim for the claim to be used. These APCs require the use of a device in the provision of the service. Moreover, in 2002, hospitals were required to bill the C code in order for the device to receive pass-through payment for the device. Therefore, if no C code was billed on the claim, we presumed that the claim was incorrectly coded, and we did not use it. For some of these APCs, we further required that specific devices be on the claim.

TABLE 10.—APCS FOR WHICH A HCPCS FOR A DEVICE WAS REQUIRED TO BE ON A CLAIM USED FOR WEIGHT SETTING

APC	APC description	Status
0032	Insertion of Central Venous/Arterial Catheter	T
0048	Arthroplasty with Prosthesis	T
0080	Diagnostic Cardiac Catheterization	T
0081	Non-Coronary Angioplasty or Atherectomy	T
0082	Coronary Atherectomy	T
0083	Coronary Angioplasty and Percutaneous Valvuloplasty	T
0085	Level II Electrophysiologic Evaluation	T
0086	Ablate Heart Dysrhythm Focus	T
0087	Cardiac Electrophysiologic Recording/Mapping	T
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	T
0090	Insertion/Replacement of Pacemaker Pulse Generator	T
0104	Transcatheter Placement of Intracoronary Stents	T
0106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	T
0107	Insertion of Cardioverter-Defibrillator	T
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	T
0115	Cannula/Access Device Procedures	T
0119	Implantation of Devices	T
0122	Level II Tube Changes and Repositioning	T
0167	Level III Urethral Procedures	T
0182	Insertion of Penile Prosthesis	T
0202	Level VIII Female Reproductive Proc	T
0222	Implantation of Neurological Device	T
0225	Implantation of Neurostimulator Electrodes	S
0226	Implantation of Drug Infusion Reservoir	T
0227	Implantation of Drug Infusion Device	T
0229	Transcatheter Placement of Intravascular Shunts	T
0259	Level VI ENT Procedures	T
0313	Brachytherapy	S
0384	GI Procedures with Stents	T
0385	Level I Prosthetic Urological Procedures	T
0386	Level II Prosthetic Urological Procedures	T
0648	Breast Reconstruction with Prosthesis	T
0652	Insertion of Intraperitoneal Catheters	T
0653	Vascular Reconstruction/Fistula Repair with Device	T
0654	Insertion/Replacement of a permanent dual chamber pacemaker	T
0655	Insertion/Replacement/Conversion of a permanent dual chamber pacemaker	T
0670	Intravenous and Intracardiac Ultrasound	S
0674	Prostate Cryoablation	T
0680	Insertion of Patient Activated Event Recorders	S
0681	Knee Arthroplasty	T

• For each single-procedure claim, we calculated a cost for every billed line item charge by multiplying each revenue center charge by the appropriate hospital-specific CCR. We used the most recent settled or submitted cost reports. Using the most recent ''submitted to settled ratio,'' we adjusted CCRs for the submitted cost reports but not the settled ones. If an appropriate cost center did not exist for a given hospital, we crosswalked the revenue center to a secondary cost center when possible, or used the hospital's overall CCR for outpatient department services. We excluded from this calculation all charges associated with HCPCS codes previously defined as not paid under the OPPS (for example, laboratory, ambulance, and therapy services). We included all charges associated with HCPCS codes that are designated as packaged services (that is, HCPCS codes with the status indicator of ''N'').

• To calculate per-service costs, we used the charges shown in revenue centers that contained items integral to performing services. Table 11 contains a list of the revenue centers that we packaged into major HCPCS codes when they appeared on the same claim. This is a change to the packaging of revenue centers by category of service that had been done since the inception of the OPPS in the April 7, 2000 final rule (65 FR 18457). In all prior years of OPPS, we had specific subsets of revenue centers that we packaged into major HCPCS codes based on the type of service we assigned to the HCPCS code for this purpose. For example, we had a set of revenue centers that could be packaged into visit codes and a different, but overlapping, set of revenue centers that could be packaged into surgery codes. We propose to convert these categories to a single set of revenue codes (*see* Table 11) that would be packaged into the major HCPCS code with which it appears on a claim. We believe that this will increase the likelihood that the total charge for the major HCPCS code will capture all of the costs attributed to the services furnished.

Table 11 lists packaged services by revenue center that we are proposing to use to calculate per-service costs for outpatient services furnished in CY 2004.

TABLE 11.—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
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)
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 standardized costs for geographic wage variation by dividing the labor-related portion of the operating and capital costs for each billed item by the proposed FY 2004 hospital inpatient prospective payment system (IPPS) wage index published in the **Federal Register** on May 9, 2002 (67 FR 31602). We used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We have used this estimate since the inception of the OPPS and continue to believe that it is appropriate. (See the April 7, 2000 final rule (65 FR 18496) for a complete description of how we derived this percentage).

• We summed the standardized labor-related cost and the nonlabor-related cost component for each billed item to derive the total standardized cost for each procedure or medical visit.

• We removed extremely unusual costs that appeared to be errors in the data using a trimming methodology analogous to what we use in calculating the diagnosis-related group (DRG) weights for the hospital IPPS. That is, we eliminated any bills with costs outside of three standard deviations from the geometric mean.

• After trimming the procedure and visit level costs, we mapped each procedure or visit cost to its assigned APC, including, to the extent possible, the proposed APC changes.

• We calculated the median cost for each APC.

To develop the median cost for observation (APC 339, HCPCS code G0244), we selected claims containing HCPCS code G0244 (Observation care

provided by a facility to a patient with CHF, chest pain, or asthma, minimum eight hours, maximum forty-eight hours) that also showed one or more of the ICD–9 (International Classification of Diseases, Ninth Edition) diagnosis codes required for payment of APC 339. We ignored other separately payable codes so that the claims with G0244 would not be excluded for having multiple major procedures on a single claim. We packaged the costs of allowable revenue centers and HCPCS codes with status indicator ''N'' into the cost of G0244, and trimmed as was done for the calculation of the median costs for other APCs.

To calculate the weights for APCs 649 (Prostate Brachytherapy with Palladium seeds) and 684 (Prostate Brachytherapy with Iodine seeds) into which the cost of brachytherapy seeds are packaged, we selected claims that contained HCPCS codes 77778 and 55859 where the lines containing codes 77778 and 55859 have the same date of service and the claim contained either HCPCS code C1720 (Palladium seeds) or C1718 (Iodine seeds) (which need not be the same date of service as 77778 and 55859). We ignored line items for services paid on the laboratory fee schedule and lines with separately payable HCPCS (even if multiple majors). We packaged all remaining costs from allowable revenue centers and packaged HCPCS into the claim (regardless of date of service). We separated the claims with Palladium seeds from claims with Iodine seeds. We then created a median cost for prostate brachytherapy with Palladium seeds (APC 0649; G0256) from the claims containing 77778, 55859, and C1720 (Palladium seeds), and we created a median cost for prostate brachytherapy with Iodine seeds (APC 0684; G0261) from claims containing 77778, 55859, and C1718 (Iodine seeds).

- Using the median APC costs, we calculated the relative payment weights for each APC. 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 2002 data, the median cost for APC 0601 is $58.78.

Section 1833(t)(9)(B) of the Act requires that APC revisions, relative payment weight revisions, and wage index and other adjustments be made in a manner that ensures that estimated aggregate payments under the OPPS for 2004 are neither greater than nor less than the estimated aggregate payments that would have been made without the changes. To comply with this requirement concerning the APC changes, we compared aggregate payments using the CY 2003 relative weights to aggregate payments using the CY 2004 proposed weights. Based on this comparison, we are proposing to make an adjustment of 1.003107132 to the weights. The weights that we are proposing for CY 2004, which incorporate the recalibration adjustments explained in this section, are listed in Addendum A and Addendum B.

IV. Transitional Pass-Through and Related Payment Issues

A. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain medical devices, 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, Public Law 107–186; current drugs, biological agents, and brachytherapy devices used for the treatment of cancer; and current drugs and biological products.

For those drugs, biological agents, and devices referred to as ''current,'' the transitional pass-through payment began on the first date the hospital OPPS was implemented (before enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA), Public Law 106–554, enacted December 21, 2000).

Transitional pass-through payments are also required for certain ''new'' medical devices, drugs, and biological agents that were not being paid for as a hospital outpatient 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 device, drug, or biological. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years.

Section 1833(t)(6)(B)(i) of the Act required that we establish by April 1, 2001, initial categories to be used for purposes of determining which medical devices are eligible for transitional pass-through payments. Section 1833(t)(6)(B)(i)(II) of the Act explicitly authorized us to establish initial categories by program memorandum (PM). On March 22, 2001, we issued two PMs, Transmittals A–01–40 and A–01–41 that established the initial categories. We posted them on our Web site at: *http://www.hcfa.gov/pubforms/transmit/A0140.pdf* and *http://www.hcfa.gov/pubforms/transmit/A0141.pdf,* respectively.

Transmittal A–01–41 includes a list of the initial device categories, a crosswalk of all the item-specific codes for individual devices that were approved for transitional pass-through payments, and the initial category code by which the cross-walked individual device was to be billed beginning April 1, 2001. Items eligible for transitional pass-through payments are generally coded using a Level II HCPCS code with an alpha prefix of ''C.'' Pass-through device categories are identified by status indicator ''H'' and pass-through drugs and biological agents are identified by status indicator ''G.'' Subsequently, we added a number of additional categories, retired 95 categories effective January 1, 2003, and made clarifications to some of the categories' long descriptors found in various program transmittals. A list of device category codes in effect as of July 1, 2003, can be found in Transmittal A–03–051, which was issued on June 13, 2003. This PM can be accessed on our Web site at *http://www.cms.gov.*

Section 1833(t)(6)(B)(ii) of the Act also requires us to establish, through rulemaking, criteria that will be used to create additional device categories. The criteria for new categories were the subject of a separate interim final rule with comment period published in the **Federal Register** on November 2, 2001 (66 FR 55850) and made final in the November 1, 2002 **Federal Register** (67 FR 66781) announcing the 2003 update to the OPPS.

Transitional pass-through categories are for devices only; they do not apply to drugs or biological agents. The regulations at § 419.64 governing transitional pass-through payments for eligible drugs and biological agents are unaffected by the creation of categories.

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

B. Discussion of 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 2004, the applicable percentage is 2.5 percent; for 2004 and subsequent years, we specify the applicable percentage up to 2.0 percent. We propose to set the percentage at 2.0 percent for the 2004 OPPS.

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 payment exceeds the applicable percentage but also to determine the appropriate reduction to the conversion factor.

For devices, making an estimate of pass-through spending in 2004 entails estimating spending for two groups of items. The first group consists of those items for which we have claims data (that is, items that were eligible in 2002 and that will continue to be eligible in 2004). The second group consists of those items for which we have no direct claims data (that is, items that became, or will become, eligible in 2003 and will retain pass-through status and items that will be newly eligible beginning in 2004).

To estimate 2004 pass-through spending for device categories in the first group, we would use volume and hospital cost (derived from charges on claims using cost-to-charge ratios) information from 2002 claims data. This information would be projected forward to 2004 levels using appropriate inflation and utilization factors. For existing categories with no claims data in 2002 that are, or will be, active in 2004, we would follow the method described in the November 2, 2001 final rule (66 FR 55857). We would use price information from manufacturers and volume estimates from claims related to procedures that use the devices in question. This information would be projected forward to 2004 using appropriate inflation and utilization factors to estimate 2004 pass-through spending for this group of categories. For categories that become eligible in 2004, we would use the same method as described for categories that were newly active in 2002. We anticipate that any new categories for January 1, 2004 will 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, 2004.

To estimate 2004 pass-through spending for drugs and biological agents, we would make estimates of utilization, collect data on average wholesale price (AWP) and combine these with ratios used to represent hospital acquisition costs for these drugs. We would collect drug-specific information on Medicare use from the pharmaceutical manufacturer where possible and rely on other sources (such as peer-reviewed clinical studies) as needed. In the past, we relied upon the AWP published in the Redbook to establish the AWP of pass-through drugs payable under the OPPS. As described elsewhere in this preamble, we plan to adopt and apply the provisions outlined in the Payment Reform for Part B drugs. For the purpose of calculating payments for transitional pass-through items, we would determine 95 percent of the drug's average wholesale price based on the newly established AWP. We would use published ratios on hospital acquisition costs reported in our proposed rule of August 9, 2002 (67 FR 52129). For sole source drugs the ratio of acquisition cost to AWP equals 0.71; for multi-source drugs, the ratio is 0.68; and for multi-source drugs with generic competitors, the ratio equals 0.46.

For drugs and biological agents that may receive pass-through status effective January 1, 2004, we propose to use the same methodology as described for drugs and biological agents that received pass-through status in 2003. Any new pass-through drugs and biological agents effective beginning in 2004 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 these drugs and biological agents made effective January 1, 2004.

After using the methodologies described above to determine projected 2004 pass-through spending for the groups of devices, drugs, and biological agents, we would calculate total projected 2004 pass-through spending as a percentage of the total projected payments (Medicare and beneficiary payments) under OPPS to determine if the pro rata reduction will be required.

Table 12 shows our current estimate of 2004 pass-through spending for known pass-through drugs, biologicals, and devices based on information available at the time this table was developed. We are uncertain whether estimated pass-through spending in 2004 will exceed $456 million (2.0 percent of total estimated OPPS spending). We have not yet completed the estimate of pass-through spending for a number of drugs and devices. In particular, we do not have estimates for those drugs still under agency review for additional pass-through payments beginning October 2003 or the changes in pass-through spending that could result from quarterly rather than annual updates of AWP for pass-through drugs. Finally, we would incorporate an estimate of pass-through spending for items for which pass-through payment becomes effective later in 2004 (that is, April 1, 2004; July 1, 2004; and October 1, 2004) based on estimates of items that become eligible for pass-through payment on October 1, 2003 and January 1, 2004. Specifically, we would assume a proportionate amount of spending for items that become eligible later in the year while making an adjustment to account for the fact that items made eligible later in the year will not receive pass-through payments for the entire year. We invite comments on the methodology as described above and the estimates for utilization that appear in the table below.

TABLE 12.—ESTIMATES FOR 2004 TRANSITIONAL PASS-THROUGH SPENDING

New HCPC	APC	Drug biological	2004 pass-through payment portion	2004 estimated utilization	2004 anticipated pass-through payments
		Existing Pass-through Drugs/Biologicals			
C9111	9111	Injection Bivalrudin, 250 mg per vial	$100.50	21,007	2,111,200
C9112	9112	Perflutren lipid microsphere, per 2 ml	$37.44	67,000	2,508,480

TABLE 12.—ESTIMATES FOR 2004 TRANSITIONAL PASS-THROUGH SPENDING—Continued

New HCPC	APC	Drug biological	2004 pass-through payment portion	2004 estimated utilization	2004 anticipated pass-through payments
C9113	9113	Inj Pantoprazole sodium, per vial	$5.76	20,000	115,200
C9116	9116	Ertapenum sodium, per 1 gm vial	$11.45	7,200	82,440
Q4053	9119	Pegfilgrastim, per 1 mg single dose vial	$118.00	662,062	78,123,329
C9120	9120	Faslodex, per 50 mg injection	$44.25	137,078	6,065,702
C9121	9121	Argatroban, per 5 mg	$3.60	50,000	180,000
C9200	9200	Orcel, per 36 cm2	$286.80	1,000	286,800
C9203	9203	Perflexane lipid microspheres, per single use vial	$36.00	82,400	2,966,400
J2324	9114	Nesiritide, per 0.5 mg vial	$36.48	60,000	2,188,800
J3315	9122	Triptorelin pamoate, per 3.75 mg	$104.90	219,600	23,036,040
J3487	9115	Zoledronic acid, 1 mg	$51.38	539,000	27,693,820
C9204	9204	Ziprasidone mesylate, per 20 mg	$10.50	117,143	1,230,000
C9205	9205	Oxaliplatin, per 5 mg	$23.86	280,756	6,698,845
HCPCS	**APC**	**Description**		**2004 estimated utilization**	**2004 anticipated payment**
		Existing Pass-through Devices			
C1783	1783	Ocular implant, aqueous drainage assist device		323	159,756
C1814	1814	Retinal tamponade device, silicone oil		35106	13,649,018
C1884	1884	Embolization Protective System		25000	38,601,544
C1888	1888	Catheter, ablation, non-cardiac, endovascular (implantable).		214	129,128
C1900	1900	Lead, left ventricular coronary venous system		2091	2,814,528
C2614	2614	Probe, percutaneous lumbar discectomy		899	1,748,555
C2632	2632	Brachytherapy solution, iodine-125, per mCi		225	1,890,000
C1818	1818	Integrated keratoprosthesis		4	27,800

V. Payment for Devices

A. Pass-Through Devices

Section 1833(t)(6)(B)(iii) of the Act requires that 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. We propose that two device categories currently in effect would expire effective January 1, 2004. Our proposed payment methodology for devices that have been paid by means of pass-through categories, and for which pass-through status would expire effective January 1, 2004, is discussed in the section below.

Although the device category codes became effective April 1, 2001, most of the item-specific ''C'' codes for pass-through devices that were crosswalked to the new category codes were approved for pass-through payment in CY 2000 and as of January 1, 2001. (The crosswalk for item-specific ''C'' codes to category codes was issued in Transmittals A–01–41 and A–01–97). We based the expiration dates for the category codes listed in Table 13, on when a category was first created, or when the item-specific devices that are described by, and included in, the initial categories were first paid as pass-through devices, before the implementation of device categories. These proposed device category expiration dates are listed in Table 13. We propose to base the expiration date for a device category on the earliest effective date of pass-through payment status of the devices that populate that category. There are two categories for devices that will have been eligible for pass-through payments for over 2 1/2 years as of December 31, 2003, and we propose that they would not be eligible for pass-through payments effective January 1, 2004. The two categories we propose for expiration are C1765 and C2618, as indicated in Table 13. Each category includes devices for which pass-through payment was first made under OPPS in 2000 or 2001.

A comprehensive list of all pass-through device categories effective on or before July 2003 is displayed in Table 13. Also displayed are the dates the devices described by the category were populated and their respective proposed expiration dates.

The methodology used to base expiration of a device category is the same as that used to determine the 95 initial categories that expired as of January 1, 2003. A list including those 95 categories that expired as of January 1, 2003 (as well as 5 categories that continue to be paid in 2003) is found in the November 1, 2002 final rule (67 FR 66761 through 66763).

TABLE 13.—LIST OF CURRENT PASS-THROUGH DEVICE CATEGORIES WITH PROPOSED EXPIRATION DATES

	HCPCS codes	Category long descriptor	Date(s) populated	Expiration date
	C1765	Adhesion Barrier	10/1/00–3/31/01; 7/1/01	12/31/03
	C2618	Probe, cryoblation	4/1/01	12/31/03
	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

TABLE 13.—LIST OF CURRENT PASS-THROUGH DEVICE CATEGORIES WITH PROPOSED EXPIRATION DATES—Continued

	HCPCS codes	Category long descriptor	Date(s) populated	Expiration date
	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

The methodology that we propose to use to package pass-through device costs is consistent with the packaging methodology that we describe in section II.B.5. For the codes in APCs displayed in Table 10, we propose to use only those claims on which the hospital included the ''C'' code and to discard the claims on which no ''C'' code is billed.

We propose to limit our analysis to the claims with ''C'' codes because we are not confident that the claims for the relevant APCs include the charges for the devices unless the ''C'' codes are specifically billed.

To calculate the total cost for a service on a per-service basis, we included all charges billed with the service in a revenue center in addition to packaged HCPCS codes with status indicator ''N.'' We also packaged the costs of devices that we propose would no longer be eligible for pass-through payment in 2004 into the HCPCS codes with which the devices were billed.

B. Expiration of Transitional Pass-Through Payments in CY 2004

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). We stated that we would package the costs of the devices no longer eligible for pass-through payments in 2003 into the costs of the procedures with which the devices were billed in 2001. There were very few exceptions to the policy (for example, brachytherapy seed for other than prostate brachytherapy), and we propose to continue this policy. Therefore, we propose that the payment for the devices that populate C1765 and C2618, which we propose will cease to be eligible for pass-through payment on January 1, 2004, would be made as part of the payment for the APCs with which they are billed.

C. Other Policy Issues Relating to Pass-Through Device Categories

Reducing Transitional Pass-Through Payments To Offset Costs Packaged Into APC Groups

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 associated devices that are eligible for pass-through payments (66 FR 59904). Beginning with the implementation of the 2002 OPPS update (April 1, 2002), we deduct from the pass-through payments for the identified devices an amount that offsets the portion of the APC payment amount that we determine is associated with 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 2003 (67 FR 66801).

For the 2002 and 2003 OPPS updates, we estimated the portion of each APC rate that could reasonably be attributed to the cost of an associated pass-through device that is eligible for pass-through payment using claims data from the period used for recalibration of the APC rates. Using these 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 associated device category ''C'' codes that were billed with the APC packaged into the median. Comparing the median APC cost minus device packaging to the median APC cost including device packaging enables us to determine the percentage of the median APC cost that is attributable to associated pass-through devices. By applying these percentages to the median APC costs, we determined the applicable offset amount. We included any APC on the offset list for which the device cost was at least 1 percent of the APC's cost.

As we discussed in our November 1, 2002 final rule (67 FR 66801), the listed offsets are those that may potentially be used because we do not know which procedures would be billed with newly created categories.

After publication of the November 1, 2002 final rule, we received a comment indicating that in some cases it may be inappropriate to apply an offset to a new device category because the device category is not replacing any device whose costs have been packaged into the APC. We agree with this comment. Therefore, we propose to modify our policy for applying offsets. Specifically, we would apply an offset to a new device category only when we can determine that an APC contains costs associated with the device. At this time, we propose to continue our existing methodology for determining the offset amount, described above. However, we solicit comments for alternative methodologies for determining the offset amounts that potentially could be applied to the payment amounts for new device categories.

We can use this methodology to establish the device offset amounts for the 2004 OPPS because we are using 2002 claims on which device codes are reported. However, for the 2005 update to OPPS, we would use 2003 claims that would not include device coding. Thus, for 2005, we are considering whether or not to use the charges from lines on the claim having no HCPCS code but have charges under revenue codes 272, 275, 276, 278, 279, 280, 289, and 624 as proxies for the device charges that would have been billed with HCPCS codes for these devices in previous years. We are also considering the reinstitution of the ''C'' codes for expired device categories and requiring hospitals to use one or more newly created ''C'' codes for identification of devices and costs on claims. See section VI.B of this proposed rule for further discussion.

We propose to review each new device category on a case-by-case basis to determine whether device costs associated with the new category are packaged into the existing APC structure.

We reviewed the device categories eligible for continuing pass-through payment in 2004 to determine whether the costs associated with the device

categories are packaged into the existing APCs. For the categories existing as of publication of this proposed rule, we have determined that there are no close or identifiable costs associated with the devices in our data related to the respective APCs that are normally billed with those devices. Therefore, for these categories we are proposing to set the offset to $0 for 2004.

If we create a new device category and determine that our data contain identifiable costs associated with the devices in any APC, we would apply an offset. We propose, if any offsets apply, for new categories, to announce the offsets in the program memorandum that announces the information regarding the new category.

VI. Payment for Drugs, Biologicals, Radiopharmaceutical Agents, Blood, and Blood Products

A. Pass-Through Drugs and Biologicals

Section 1833(t)(6)(D)(i) of the Act requires us to make transitional pass-through payment for new drugs equal to the amount by which 95 percent of the average wholesale price (AWP) of the drug exceeds the proposed payment rate. In the past, we have used the AWP published in the Red Book to determine payment amounts for pass-through drugs as we explain in the correction notice issued on February 10, 2003 (68 FR 6637). However, we are concerned about the extent to which Medicare pays more for drugs than other payers and more than the market-based price of drugs. To address this problem of how to pay appropriately for drugs that are priced using the AWP, we are developing regulations that would revise the current payment methodology for part B covered drugs paid under section 1842(o) of the Act. When the AWP regulations are made final, we propose to adopt and apply the provisions of the final AWP rule to establish the AWP of pass-through drugs payable under the OPPS. If implementation of the AWP final rule necessitates mid-year changes in the 2004 OPPS payment rates for pass-through drugs, we propose to make those changes on a prospective payment basis through our regular OPPS PM and PRICER quarterly updates. We further propose to issue instructions by program memorandum regarding implementation of the provisions of the AWP final rule to set payment rates for pass-through drugs under the OPPS.

An AWP final rule could be published before 2004. However, if the AWP final rule is not issued in time to permit us to apply its provisions to price pass-through drugs furnished on or after January 1, 2004, we propose to use 95 percent of the AWP listed in the most recent quarterly update of the Single Drug Pricer (SDP). In the past, we have relied solely on the Red Book to determine the AWP for a pass-through drug, as we explain in the correction notice issued on February 10, 2003 (68 FR 6637). However, on January 1, 2003, we introduced for the first time a single pricing source for approximately 400 drugs and biologicals for which the Medicare payment allowance is based on 95 percent of their AWP. We established the SDP to address apparent discrepancies in drug pricing that were the unintended result of delegating calculation of AWP to multiple contractors, whose application of the pricing methodology established under 42 CFR 405.517 sometimes varied. The SDP continues to rely on published compilations such as the Red Book and First Data Bank to identify wholesale drug prices. However, using the SDP enables us to establish a uniform Medicare payment allowance for drugs whose payment is based on 95 percent of their AWP, which results in greater consistency in Medicare drug pricing nationally. If a drug with pass-through status is not included in the SDP, we propose to forward to the SDP contractor the AWP information submitted as part of the pass-through application.

Because the January SDP would not be available in time, we propose to announce the January 1, 2004 prices for pass-through drugs in our January 2004 OPPS implementing instructions to fiscal intermediaries and in the January 2004 OPPS PRICER rather than in the 2004 final rule, which is to be published in the **Federal Register** by November 1, 2003. We further propose to update the AWP for pass-through drugs paid under the OPPS on a quarterly basis in accordance with the quarterly updates of the SDP. The updated rates for pass-through drugs and biologicals would also be issued through our quarterly OPPS program memoranda and PRICER updates.

Additional information regarding the SDP can be found on the CMS Web site in Program Memorandum AB–02–174, issued December 3, 2002.

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

1. Background

Under the OPPS, we currently pay for radiopharmaceuticals, drugs, and biologicals including blood, and blood products, which do not have pass-through status, in one of three ways: packaged payment, separate payment (individual APCs), and reasonable cost. As we explained in the April 7, 2000 final rule (65 FR 18450), 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 such packaged items and supplies whose costs are recognized and paid for within the national OPPS payment rate for the associated procedure or service. (Transmittal A–01–133, a Program Memorandum issued to Intermediaries on November 20, 2001, explains in greater detail the rules regarding separate payment for packaged services). As we explained in the November 1, 2002 final rule (67 FR 66757), we do not classify diagnostic and therapeutic radiopharmaceutical agents as drugs or biologicals as described in section 1861(t) of the Act.

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 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 1, 2002 final rule (67 FR 66774), we packaged payment for drugs and radiopharmaceuticals into the APCs with which they were billed if the median cost per line for the drug or radiopharmaceutical was less than $150, and we established a separate APC payment for drugs and radiopharmaceuticals for which the median cost per line exceeded than $150. This supported our general view that payment for drugs and radiopharmaceuticals should be made as part of the payment for the services in which they are used in order to encourage efficient purchase and use of drugs and radiopharmaceuticals provided in the hospital outpatient department.

Payment Rates for 2003

To limit the dramatic reduction in payment rates for many of the separately payable drugs and radiopharmaceuticals from 2002 to 2003, we limited the decrease in their median costs from 2002 median costs to 15 percent plus half of the difference between the total proposed reduction and 15 percent reduction. (For example, for a drug whose cost decreased by 35 percent from the applicable 2002 median cost, the allowed reduction from 2002 to 2003 was 15 percent plus (½ times 35–15) percent = 25 percent.) For each blood and blood product, we provide separate payment in an individual APC and limited any decrease in payment rate from 2002 to 2003 to 15 percent. In 2003, we also excluded from OPPS certain vaccines and orphan drugs (that met our orphan criteria) and paid for these items at reasonable cost. Our intent in implementing these policies was to avoid adversely affecting beneficiary access to needed treatment.

Drugs for Which We Propose Pass-Through Status Will Expire in 2004

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 nor any longer than 3 years. The drugs that are due to expire December 31, 2003 meet that criterion. Table 14 lists the drugs and biologicals for which we propose pass-through status will expire on December 31, 2003.

TABLE 14.—PROPOSED LIST OF DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH STATUS EXPIRES CY 2004

HCPCS	APC	Long descriptor	Trade name	Proposed pass-through Expiration date
A9700	9016	Injection, Octafluoropropane, per 3 ml	Optison (single source)	12–31–03
J0587	9018	Injection, Botulinum toxin, type B, per 100 units.	Myobloc (single source)	12–31–03
J0637	9019	Injection, Caspofungin acetate, 5 mg	Cancidas (single source)	12–31–03
J7517	9015	Mycophenolate mofetil, oral per 250 mg	CellCept (single source)	12–31–03
J9010	9110	Injection, Alemtuzumab, per 10 mg	Campath (single source)	12–31–03
J9017	9012	Injection, Arsenic trioxide, per 1 mg	Trisenox (single source)	12–31–03
J9219	7051	Implant, Leuprolide acetate, per 65 mg implant.	Viadur (single source)	12–31–03
C9201	9201	Dermagraft, per 37.5 sq. centimeters	Dermagraft (single source)	12–31–03

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

To the maximum extent possible, our intention is to package into the APC payment the costs of any items and supplies that are furnished with an outpatient procedure. We considered several options for packaging in 2004 and propose the following policy:

For 2004, we propose to continue with our policy of paying separately for drugs and radiopharmaceuticals whose median cost per day exceeds $150 and packaging the cost of drugs and radiopharmaceuticals with median cost per day of less than $150 into the procedures with which they are billed.

As discussed in the November 1, 2002 final rule, we received several comments on our methodology of analyzing single line items on drug claims for the 2003 OPPS (67 FR 66772). Commenters stated that our methodology was not consistent with how hospitals bill for certain drugs, biologicals, and radiopharmaceuticals. They believe that this inconsistency affected whether or not a drug, biological, or radiopharmaceutical fell below the $150 median cost per line threshold. Commenters claimed that we incorrectly assumed ''that a single administration of a drug was billed as a single line item on a claim.'' These commenters alleged that hospitals often bill for certain drugs administered during a single patient encounter using multiple lines on a claim. For example, if 10 units of a drug were administered at a cost of $100 but the hospital billed 2 line items of 5 units at a cost of $50 each, then a methodology that determines median costs on a per line basis would incorporate 2 line items at $50 when the real cost was one line item at $100. If a significant percentage of administrations for this drug was billed in this manner, it would result in median costs that underestimate the true cost of the drug. We agree with this comment. Therefore, we propose to change our packaging methodology to account for such hospital billing practices.

We calculated the median cost per day using claims data from April 1, 2002 to December 31, 2002 for all drugs and radiopharmaceuticals paid under the OPPS that had a HCPCS code during this time period including drugs for which transitional pass-through payment ended on January 1, 2003. Although we included orphan drugs in this methodology, we discuss them separately below. We excluded from these calculations vaccines and blood and blood products that are discussed below. In order to calculate the median cost per day for the drugs, biologicals, and radiopharmaceuticals, we took the following steps:

- After application of the cost-to-charge ratios, we aggregated all line items for a single date of service on a single claim for each drug or radiopharmaceutical. This resulted in creating a single line item with the total number of units and the total cost of a drug or radiopharmaceutical given to a patient in a single day.
- A separate record was then created for each drug or radiopharmaceutical by date of service, regardless of the number of lines the drug or radiopharmaceutical was billed in each claim. For example, drug X is billed on a claim with two different dates of service, and for each date of service, the drug is billed on 2 line items with costs of $10 and 5 units in each line item. In this case, the computer program would have created two records for this drug, and each record would have a total cost of $20 and 10 units.
- For each record created for a drug or radiopharmaceutical, the cost per unit of the drug was calculated. If drug X's descriptor is ''per 1 mg'' and one record was created for a total of 10 mg (as indicated by the total number of units for the drug on the claim for each unique date of service), then the computer program divided the total cost for the record by 10 to give a per unit cost. This unit cost was then weighted by the total number of units in the record. This was done by generating a number of line items equivalent to the number of units in that particular claim. Thus, a claim with 100 units and a total cost of $200 would be given 100 line items each with a cost of $2 while a

claim of 50 units with a cost of $50 would be given 50 line items each with a cost of $1.

- The unit records with cost per unit greater or less than 3 standard deviations from the geometric mean were then trimmed.
- The remaining unit observations were arrayed and the median cost per unit of the drug or radiopharmaceutical was established.
- Next, the total number of units billed on all claims for the drug or radiopharmaceutical was divided by the total number of unique per-day records for the drug or radiopharmaceutical to arrive at an average number of units per day.
- The average number of units per day for each drug or radiopharmaceutical was then multiplied by the median cost per unit to arrive at its ''median cost'' per day.
- We then arrayed the median cost per day for all drugs and radiopharmaceuticals in ascending order and examined the distribution.

Many commenters have alleged that hospitals do not accurately bill the number of units for drugs and radiopharmaceuticals. Because this methodology assumes that hospitals bill the number of units accurately, we compared the median cost per day obtained by the above methodology with the median cost per day derived as follows: We aggregated line items as above and created records for each drug and radiopharmaceutical based on date of service. However, instead of calculating costs on a per-unit basis, we simply reduced total charges to total costs for each record and determined the median. This methodology assumes that hospitals record charges more accurately than units. We believed that calculating median costs using the second methodology would address the concerns of commenters and would help us determine whether our median cost per unit calculation accurately reflected the costs of drugs and radiopharmaceuticals.

In most cases, the median costs determined by the two methodologies were similar. Based on this comparison, we believe that calculating median costs per unit accurately reflects the actual cost of the drug or radiopharmaceutical. Furthermore, given the wide variability of doses used for many drugs, we believe that it is important to pay on a ''per unit'' basis for separately payable drugs and radiopharmaceuticals. For example, many chemotherapy agents are dosed based on both body area and frequency of administration. Thus, a patient with a body area of 2 m squared could receive 600 mg of a drug every 3 weeks, 400 mg every 2 weeks, or 200 mg every week depending on the chemotherapy regimen.

Based on our analyses, we believe that it is reasonable to continue our current policy of packaging drugs and radiopharmaceuticals with a median cost of less than $150 per day. This means that approximately 52 percent of the drugs and radiopharmaceuticals will be packaged and 48 percent of the drugs and radiopharmaceuticals will be paid separately.

We noticed that several drugs and radiopharmaceuticals with median cost per line that were under $150 for the 2003 OPPS have median costs per day that are equal to or greater than $150 based on the data used for the 2004 OPPS. For some other drugs and radiopharmaceuticals, we saw that their median costs per line were equal to or greater than $150 for 2003 OPPS; however, using the 2002 data, their median costs per day fell below $150. These shifts from 2003 to 2004 would affect packaging decisions for a number of drugs.

Given that these variations exist, we propose to provide an exception in 2004 to the packaging rule for drugs and radiopharmaceuticals whose payment status would change as a result of using newer data and a different methodology. As we explain elsewhere in this proposed rule, we expect to use additional 2002 claims data for the establishment of our final policies for CY 2004. Based on this additional data and comments from the public, we intend to re-evaluate whether to package or pay separately for drugs for which the per-day median cost would cross the threshold from 2003 to 2004. For 2004, we propose that:

- Currently packaged drugs and radiopharmaceuticals with median costs per day that are at or above $150 would receive separate payment in 2004.
- Currently separately payable drugs and radiopharmaceuticals with median costs per day that are under $150 would continue to receive separate payment in CY 2004.
- Drugs whose pass-through status would expire on December 31, 2003, and whose median costs per day are under $150 would receive separate payment in 2004.
- Currently packaged drugs and radiopharmaceuticals with median costs per day below $150 would remain packaged in 2004.

We request comments on the methodology we used to determine the median cost per day, on the threshold we propose to use for packaging drugs and radiopharmaceuticals, and on the proposal to pay separately for drugs and radiopharmaceuticals whose payment status would change based on use of recent claims data and our proposed methodology.

Although in the future we expect to expand packaging the costs of drugs and radiopharmaceuticals into the APCs for the services with which they are billed, we request comments on alternatives to packaging.

3. Payment for Drugs, Biologicals, and Radiopharmaceuticals That Are Not Packaged

For the 2003 OPPS, the APC payment rate for separately payable drugs and radiopharmaceuticals with status indicator ''K'' is based on a relative weight calculated in the same way that the relative weights for procedural APCs are calculated. As with procedural APCs, we observed a decrease in the proposed payment rates for many separately payable drugs and radiopharmaceuticals; therefore, we dampened the payment reduction for APCs whose median costs decreased by more than 15 percent from 2002 to 2003.

In order to establish payment rates for separately payable drugs and radiopharmaceuticals for the 2004 OPPS, we first determined each drug's and radiopharmaceutical's median cost as described above. When we compared the median cost per unit used for determining the 2003 payment rate (for example, the true or dampened median cost) for separately payable drugs and radiopharmaceuticals with their 2004 median cost per unit, we found fluctuations in costs from 2003 to 2004.

CY 2004 median costs decreased more than 15 percent from the corresponding 2003 median cost for many of the separately payable drugs and radiopharmaceuticals. Many of these decreases affected low-volume drugs and radiopharmaceuticals and may be the result of inaccurate coding. Similarly, the 2004 median costs increased by more than 15 percent from the corresponding 2003 median cost for approximately 12 (mostly low volume) drugs and radiopharmaceuticals. For many of the high-volume, separately payable drugs and radiopharmaceuticals, the 2004 median costs increased or decreased by less than 15 percent as compared to the corresponding 2003 median cost. We solicit comments concerning the reasons for the fluctuations in median costs from 2003 to 2004. We are interested in determining whether these fluctuations reflect changes in the market prices of these drugs and radiopharmaceuticals or problems in the hospital claims data (for example, inaccurate coding, improper

charges) that we use for setting payment rates.

We considered several options to address the fluctuations in median costs for separately payable drugs and radiopharmaceuticals. One option was to base payment on our 2002 claims data without modification. A second option was to adopt for 2004 the same methodology that we used to moderate payment decreases in 2003.

A third option was to create drug and radiopharmaceutical cost bands for separately payable drugs and radiopharmaceuticals (for example, all drugs with median costs per unit of $60.01 to $70 would be assigned a proxy median of $70), which would be based on their median costs calculated using 2002 claims data. We considered adopting two sets of cost bands: one for separately payable drugs and biologicals other than radiopharmaceutical agents and one for separately payable radiopharmaceutical agents. The cost bands for drugs and radiopharmaceuticals would be assigned based solely on cost, with no consideration given to the therapeutic use or chemical composition of the drug.

When we applied the dampening methodology used for the 2003 OPPS to drugs and radiopharmaceuticals that will be separately payable in 2004, we observed that this methodology did not sufficiently limit payment reductions for many of the drugs and radiopharmaceuticals with large decreases in median cost from 2003 to 2004. Therefore, a fourth option that we considered and are proposing for 2004 is a variation of the methodology used for the 2003 OPPS. For separately payable drugs and radiopharmaceuticals whose 2004 median costs decreased by more than 15 percent from the applicable 2003 median cost, we propose to limit the reduction in median costs to one fourth of the difference between the value derived from claims data and a 15 percent reduction (for example, for a drug whose cost decreased by 35 percent from the applicable 2003 median cost, the allowed reduction from 2003 to 2004 would be 15 percent + (¼ times 35 − 15) percent = 20 percent). For separately payable drugs and radiopharmaceuticals whose median costs decreased by less than 15 percent from 2003 to 2004, we propose to establish their payment rates using the median costs derived from the 2002 claims data. We believe that it is appropriate to determine payment rates based on our claims data where those data show the cost of drugs and radiopharmaceuticals to be stable over 2 years. In cases where costs show significant fluctuation, we believe it is appropriate to mitigate the potential for underpayment. We believe our proposal bases payment rates on our claims data as required by statute and addresses the potential for making underpayments. However, based on more complete claims data we expect to have for the final rule and on the comments from the public, we will re-evaluate the appropriateness of adjusting median costs for drugs for which median costs would decline in 2004.

We also propose a separate payment policy, which is described below, for drugs, biologicals, and radiopharmaceuticals that have generic alternatives approved by the Food and Drug Administration (FDA) between October 2001 and December 2002.

We solicit comment on both our proposed methodology and payment rates for separately payable drugs and radiopharmaceuticals for 2004. Commenters who disagree with the proposed rate for a drug or radiopharmaceutical should submit verifiable information that shows our payment rate does not reflect the price that is widely available to the hospital market. Thus, information should demonstrate actual, market-based pricing of drugs and radiopharmaceuticals and should be prices at which a broadly based, national sample of hospitals are routinely able to procure the drug or radiopharmaceutical. We do not consider the published average wholesale price (AWP) for a drug to be an indication of its market-based price.

4. Proposed Payment Methodology for Drug Administration

Currently, payment for drug administration is made separately using HCPCS codes Q0081, Q0083, Q0084, Q0085, 90782, 90783, 90784, and 90788 with certain drugs packaged into the median cost for administration. The amount packaged should reflect the costs of the packaged drugs in relation to the frequency with which they are administered. Each of these codes is to be reported once per visit no matter how many drugs are administered. When a hospital administers only packaged drug(s), the appropriate HCPCS code is reported once and no separate payment is made for the drugs. When a hospital administers only separately payable drug(s) the appropriate HCPCS code is reported once; in addition, separate payment is made for the drugs. Because the payment for administration includes payment for packaged drugs, a hospital receives inappropriate reimbursement every time it administers a separately payable drug.

In order to facilitate accurate payments for drugs and drug administration, we are considering whether to make several changes in our current payment policy with regard to payment for Q0081, Q0083, Q0084, and Q0085. We are not considering changes to payment policy for HCPCS codes 90782, 90783, 90784, and 90788 at this time, although we are interested in receiving comments regarding payment for these codes.

We are proposing to continue our current policy of packaging drugs and radiopharmaceuticals that cost less than $150 per episode of care into the APC with which they are associated (for example, nuclear medicine scans, drug administration).

We are considering whether and how to make different payments to hospitals for administration of packaged drugs and administration of unpackaged drugs. We would like to ensure that when a hospital administers a separately paid drug, it would receive payment for the drug and the drug administration, but not for any drugs packaged into the administration. We also would like to ensure that the payments that are made for administration of packaged drugs are appropriate for the costs of the drugs as well as the cost of the administration.

In order to achieve the above objectives, we considered several coding and payment options and analyzed our claims data for the period April 1, 2002 through December 31, 2002.

Summary of Findings and Alternatives

As explained in greater detail below, we carefully examined data for administration of packaged and separately paid drugs billed under Q0081, Q0083, Q0084 and Q0085. We found that the data showed that paying based on a median cost for the APC for each of the current four codes generally results in underpayment when packaged drugs are billed on the claim and overpayment when separately paid drugs are billed on the claim. In the sections that follow, we discuss our data analysis in detail. We also discuss four alternatives to the current codes and APC payments in detail. In summary, those alternatives are:

1. Maintain the current codes and APCs with payments based on the median costs of all claims in the APC.

2. Eliminate the four current codes and create eight new codes to enable hospitals to report that they administered a packaged drug or a separately paid drug. We would pay a different APC amount for each of the

eight new codes. The new code descriptors would parallel those of the current codes. This would retain the concept of using one code rather than two when both ''infusion'' and administration of chemotherapy by ''other than infusion'' occurred (as exists under the current codes). Coders would have to look up the drugs administered to know which code to bill.

3. Eliminate the four current codes and create six new codes to enable hospitals to report that they administered a packaged drug or separately paid drug and pay a different APC amount for each of the six new codes. In this option, no code equivalent to Q0085 would exist. Therefore, when administering chemotherapy by ''infusion'' or ''other than infusion,'' hospitals would report two codes, one for administration by ''infusion'' and one for administration by ''other than infusion.'' This would eliminate the need to use one code when both infusion and another method of administration of chemotherapy occurred. Coders would have to look up the drugs administered to know which code to bill.

4. Retain three of the current codes (Q0081, Q0083, and Q0084) but delete Q0085 (infusion and other administration of chemotherapy) and modify the OCE to use the drugs billed on the claim to assign an APC for packaged drugs or an APC for separately paid drugs. No drug administration code could be paid without a drug also being reported on the claim.

Claims Data Analysis

Using our methodology for creating single procedure claims, we looked at all single claims for HCPCS codes Q0081, Q0083, Q0084, and Q0085. We created separate files for each HCPCS code and further subdivided those into four subgroups for each code. The subgroups were for the HCPCS code billed (1) without any HCPCS for drugs; (2) with HCPCS only for packaged drugs; (3) with HCPCS only for separately payable drugs; and (4) with HCPCS for both packaged and separately packaged drugs.

We then reviewed the median costs for each of these subgroups and determined that we could use these subgroups to create two median costs for each existing administration HCPCS code (Q0081, Q0083, Q0084, and Q0085). See Table 15 for median cost data for HCPCS subgroups. We used claims where packaged drugs appeared (subgroups W and X) to create a median cost for administration of packaged drugs. We used claims without HCPCS codes for drugs and claims with HCPCS for only separately payable drugs (subgroups Y and Z) to create a median cost for the administration of separately payable drugs.

We believe that the resultant median costs accurately reflect the costs of packaged drugs and the costs of administration of separately payable drugs. It is obvious that there are significant differences in median costs of services within the same drug administration code, depending on whether a packaged or separately paid drug was administered, the type of drug administered (chemotherapy versus non-chemotherapy) and the route of administration (infusion versus other route or both).

TABLE 15.—MEDIAN COSTS BY TYPES OF DRUGS ON THE CLAIM

HCPCS	Description	Neither packaged nor separate drug (W)	With packaged drug but no separate drug (X)	No packaged drug but with separate drug (Y)	Both packaged drug and separate drug (Z)
Q0081	Infusion therapy other than chemo	$104.97	$276.98	$117.89	$231.56
Q0083	Chemotherapy other than infusion	35.16	119.88	42.26	188.98
Q0084	Chemotherapy by infusion	127.34	250.97	159.01	265.46
Q0085	Chemotherapy by both infusion and other	97.11	154.01	203.43	318.05

We then calculated medians for circumstances in which there were neither packaged nor separately paid drugs on the claim, and there were no packaged drugs, but there were separately paid drugs on the claim (both W and Y). We also calculated medians for circumstances in which there were packaged drugs on the claim (both X and Z). The resultant medians and the number of claims used to set the medians appear in Table 16 below with the HCPCS medians for all claims (packaged and separately paid drugs together).

TABLE 16.—NUMBERS OF CLAIMS AND MEDIANS BY CODE

HCPCS code	Number of claims with packaged drugs	Median of claims with packaged drugs	Number of claims with no drug or separately paid drug	Median for claims with no drug or separately paid drug	HCPCS Median for all claims for 2004
Q0081	19,116	$274.47	280,939	$107.93	$115.11
Q0083	8,681	125.86	24,710	39.10	48.25
Q0084	34,085	257.57	23,933	142.38	205.70
Q0085	17,749	303.87	3,242	126.55	267.63

Review of the data reveals that the median costs for all claims for Q0081 and Q0083 more closely reflect the median cost of claims where no drug or only separately payable drugs were on the claim because that subset of claims represents the vast majority of claims for Q0081 and Q0083. Therefore, if we do not differentiate payment for Q0081 and Q0083 based on whether or not a packaged drug was administered, we would underpay the cases in which a packaged drug was administered. The opposite is true of Q0084 and Q0085 in which more claims reflect packaged drugs than separately paid drugs, and, therefore, the claims with packaged drugs will determine the median cost for the code, thus overpaying cases in which the drug is separately paid.

We also examined the mean and median number of drugs billed with each of the Q codes when only packaged drugs were billed, only separately paid drugs were billed, and both packaged and separately payable drugs were billed (see Table 17). With the exception of Q0085, we believe the data on the number of drugs billed per claim is consistent with the cost data in Table 15. Again, with the exception of Q0085, we are confident that the cost of packaged drugs is accurately reflected in the median cost of the codes for administration of packaged drugs. We are also confident that the median cost for administration of separately payable drugs is appropriate.

TABLE 17.—NUMBERS OF DRUGS BILLED PER SPECIFIED CODES

HCPCS	Mean number of drugs packaged	Median number of drugs packaged	Mean number of drugs separately paid	Median number of drugs separately paid
Q0081	1.05	1	1.01	1
Q0083	1.77	2	1.02	1
Q0084	1.68	1	1.10	1
Q0085	2.33	2	1.19	1

We have some concerns about the cost data for Q0085. The cost for administration of only separately payable drugs is less than the comparable cost for Q0084 ($126 vs. $142). This is counterintuitive as Q0085 describes administration of, at minimum, two drugs, while Q0084 describes administration of one or more drugs. These cost data for Q0085 also raise the concern that proper usage of the code is not understood by hospitals and, therefore, the data are not being used properly.

We believe our analysis supports the need for creating different payment amounts for the administration of packaged drugs and for the administration of separately payable drugs (and, in the case of Q0081, the administration of no drug).

While reviewing options for coding and payment for drug administration we kept five major considerations in mind:

1. Ensuring beneficiary access to drugs.
2. Making accurate payment for both packaged and separately payable drugs.
3. Collecting sufficient data on drugs and drug administration to ensure that future policy development in this area will be properly informed.
4. Facilitating proper coding by hospitals.
5. Avoiding complicated billing rules and hospital burden to the extent possible.

We thought that three basic coding and payment options were available:

1. Continuing the current coding structure and payment policy (for example, a single payment for drug administration per day no matter how many drugs were administered). (Option 1 below).
2. Creation of new codes and new payment policy to describe drug administration (for example, different sets of codes for administration of packaged and separately payable drugs along with allowance for more than one payment for drug administration per day). (Options 2 and 3 below).
3. Continuation of the current drug administration codes but creating new payment policy (for example, allowance for more than one payment for drug administration per day).

After reviewing these three basic options, we developed more fully four specific options. Under all of these options, hospitals would be required to bill all drugs using the HCPCS code for the drug.

Moreover, although we have included an expanded option for Q0085 (Chemotherapy by both infusion and other technique) in option 2, and have retained Q0085 in option 1, we have serious concerns about the extent to which Q0085 is used correctly and about the extent to which the data for this code validly reflect the costs of an identifiable service. Hence, we are particularly interested in comments regarding whether we should eliminate Q0085. (Option 4 below).

Option 1—Retain the current codes and continue to pay on a per-visit basis, based on median costs for each code regardless of whether or not packaged or separately paid drugs are administered.

We would retain the current codes, use all claims for these services to set a relative weight, and make a single payment based on the median costs for the code regardless of whether or not packaged or separately paid drugs are administered. This would result in significant underpayment for administration of packaged drugs because the largest volume of claims with this code are either for administration of no drug (Q0081) or for drugs that are separately paid (and have no packaged drug costs). See Table 16 for the median costs determined on the basis of all claims for the existing codes. We would require hospitals to report HCPCS codes for both packaged and separately payable drugs in order to inform future policy decisions in this area.

We do not propose payment amounts for this option because the budget neutrality scalar would be different under this proposal than under option 2 (which was used in the scalar and impact analysis).

Option 2—Create eight new drug administration codes to enable hospitals to report administration of both packaged and separately payable drugs.

We would create two new sets of HCPCS codes to describe administration of packaged and separately payable drugs. Each of the eight codes would have its own APC payment. The descriptions and median costs for these proposed codes would be as follows:

TABLE 18.—MEDIAN COSTS OF PROPOSED G CODES UNDER OPTION 2

HCPCS	2004 APC	2004 SI	Description	Median costs
GXXX1	0382	S	Infusion of packaged non-cancer chemotherapy drug(s), per day.	$274.47
GXXX3	0376	S	Administration of packaged cancer chemotherapy drug(s) by other than infusion, per day.	125.86

TABLE 18.—MEDIAN COSTS OF PROPOSED G CODES UNDER OPTION 2—Continued

HCPCS	2004 APC	2004 SI	Description	Median costs
GXXX4	0378	S	Administration of packaged cancer chemotherapy drug(s) by infusion, per day.	257.57
GXXX5	0380	S	Administration of packaged cancer chemotherapy drugs by both infusion and other than infusion, per day.	303.87
GYYY1	0383	S	Infusion of separately payable non-cancer chemotherapy drug(s) or non-drug infusion therapy, per day.	107.93
GYYY3	0377	S	Administration of separately payable cancer chemotherapy drug(s) by other than infusion, per day.	39.10
GYYY4	0379	S	Administration of separately payable cancer chemotherapy drug(s) by infusion, per day.	142.38
GYYY5	0381	S	Administration of separately payable cancer chemotherapy drugs by both infusion and other than infusion, per day.	126.55

The median costs for administration of packaged drugs would be determined from claims that contain at least one packaged drug and the median costs for administration of separately payable drugs (or no drugs in the case of Q0081) would be determined from claims that contained only separately payable (or no) drugs.

Although payment would not depend on accurate reporting of HCPCS codes for drugs, we would require hospitals to use HCPCS codes for both packaged and separately payable drugs in order to ensure that we had reliable data upon which to base future relative weights for these services. As described under option 4, we would create six lists of drugs in order to facilitate proper payment in the future.

Hospitals would report the appropriate code for the type of drug administered and the route(s) of administration. In this option, hospitals could bill for administration of both chemotherapy agents and administration of non-chemotherapy agents (or non-drug infusions). We would permit a maximum of one chemotherapy and one non-chemotherapy administration per day.

We are concerned that creation of these codes could require complicated billing rules and cause burden to hospitals. We would need to specify how to bill different combinations of route and category of drug (for example, two infused drugs, one pushed drug, antiemetics, and hydration). Because hospital billers would have to review both the type of administration and the type of drug administered to determine the correct code to bill, we are concerned about the potential for miscoding (with resultant mispayment) under this option, and we solicit comments on both of these issues. In some cases, this additional coding burden might result in less payment for administration (particularly Q0081).

Under this option, all codes would have a status indicator of S, and no multiple procedure reductions would apply.

This option is modeled for purposes of the budget neutrality scalar and the impact analysis (*see* Table 18).

Option 3—Create six new drug administration codes to enable hospitals to report administration of both packaged and separately payable drugs.

This option is similar to option 2 except that we would eliminate the codes used to describe administration of chemotherapy by both infusion and other techniques. Where a code is billed with a packaged drug suitable for the code, we would pay the APC for the packaged drug. Where both a packaged drug and a separately paid drug were administered via the same route of administration (and therefore only one code was billed), we would pay the APC only for the administration of the packaged drug and would pay separately for the separately paid drug and would not pay the APC for administration of the separately paid drug. Under this option, we would allow up to three payments for administration of drugs or infusions. We would allow one payment for non-chemotherapy drugs/infusions (for example, antiemetics, fluids), one payment for chemotherapy administered by infusion, and one payment for chemotherapy administered by ''other than infusion.'' As stated above, we would not allow payment for administration of packaged chemotherapy drugs by infusion and payment for administration of separately payable chemotherapy by infusion. This coding scheme would allow us to more accurately recognize the true costs of administering multiple drugs. For example, there are some economies of scale when infusing two or more drugs (for example, only one I. V. line needed), but each drug requires its own mixing and nursing care. This option would allow up to three payments for administration of drugs or non-drug infusion, thereby recognizing the unique costs of administering each drug while not making duplicate payment. In order to ensure that we do not make duplicate payment for patients receiving chemotherapy drugs and non-chemotherapy drugs (and/or hydration), we would pay GXXX1 and GYYY1 at 50 percent of their payment when one of these codes is paid in addition to chemotherapy administration (GXXX3, GXXX4, GYYY3, and GYYY4). This is because we believe there are economies of scale achieved for multiple drug administrations and that the additional resources used to provide non-chemotherapy treatment are minimal.

Following are examples of how payment would be made:

- When both packaged and separately payable chemotherapy drugs are infused, we would make payment for GXXX4—Administration of packaged chemotherapy drugs by infusion and for each separately payable chemotherapy drug, but we would not make payment for GYYY4—Infusion of separately payable chemotherapy drugs.
- When packaged chemotherapy drugs are pushed and infused, and separately payable chemotherapy drugs are infused, we would make payment for GXXX3 and GXXX4 and for each separately payable chemotherapy drug, but we would not make payment for GYYY4.
- When packaged chemotherapy drugs are infused and pushed; separately payable chemotherapy drugs are infused and packaged; and separately payable non-chemotherapy drugs are infused (for example, antiemetics), and hydration is given; we would make payment for GXXX3, GXXX4, each separately infused chemotherapy drug, GXXX1, and each separately payable non-chemotherapy drug. We would not make payment for GYYY1 or GYYY3. Note that payment for GXXX1 in this case would be made at 50 percent because it was billed with chemotherapy (if it was billed without

chemotherapy, then payment would be made at 100 percent).

Medians for these codes would be as follows:

TABLE 19.—MEDIAN COSTS UNDER OPTION 3

HCPCS	2004 APC	2004 SI	Description	Median costs
GXXX1	XXX1	T	Infusion of packaged non-cancer chemotherapy drug(s), per day.	$274.47
GXXX3	XXX3	S	Administration of packaged cancer chemotherapy drug(s) by other than infusion, per day.	125.86
GXXX4	XXX4	S	Administration of packaged cancer chemotherapy drug(s) by infusion, per day.	257.57
GYYY1	YYY1	T	Infusion of separately payable non-cancer chemotherapy drug(s) or non-drug infusion therapy, per day.	107.93
GYYY3	YYY3	S	Administration of separately payable cancer chemotherapy drug(s) by other than infusion, per day.	39.10
GYYY4	YYY4	S	Administration of separately payable cancer chemotherapy drug(s) by infusion, per day.	142.38

As modeled, these codes would have status indicator S (except as described above for GXXX1 and GYYY1).

Similar to option 2, we would require hospitals to report HCPCS codes for packaged and separately payable drugs to ensure that we have reliable data upon which to base future relative weights for these services. As described under option 4, we would create six lists of drugs in order to facilitate proper coding and payment in the future.

We do not propose payment amounts for this option because the budget neutrality scalar would be different under this proposal than under option 2 (which was used in the scalar and impact analysis).

Option 4—Use of codes Q0081, Q0083, and Q0084 and deletion of Q0085 with creation of logic in the outpatient code editor (OCE) to enable differential payment for administration of packaged and separately payable drugs.

This option is similar to option 3 in terms of payment policy. However, instead of creating six new codes, hospitals would continue to report codes Q0081, Q0083, Q0084, and the HCPCS codes for all packaged and separately payable drugs. We would delete Q0085 in order to simplify hospital reporting and to facilitate creation of payment logic in the OCE.

We would create six lists of drugs (see Addenda L, M, N, O, P, Q): packaged chemotherapy agents administered by other than infusion, separately payable chemotherapy agents administered by other than infusion, packaged chemotherapy agents administered by infusion, separately payable chemotherapy agents administered by infusion, packaged non-chemotherapy agents administered by infusion, and separately payable non-chemotherapy agents administered by infusion. These lists would be coded into the OCE, and would be updated quarterly by program memoranda. We realize that a few drugs may be administered by both infusion and other techniques. In these lists, we would assign each drug to its predominant form of administration in a hospital outpatient setting. If we could not determine whether a drug was infused or administered by a technique other than infusion (for example, we receive a claim with Q0083 and Q0084 and two drugs that may be administered by either infusion or another technique), we would associate each drug with its predominant administration code.

We would create logic in the OCE that would base payment on the combination of administration and drug codes on the claim but would only allow one unit of each administration type as described in option 3. The medians for the APCs to which OCE would assign the codes are described in Table 20.

TABLE 20.—MEDIANS FOR APCS UNDER OPTION 4

Drug administration codes on the claim	Nonchemo drug, packaged list (subgroup X)	Chemo drug, packaged list (subgroup W)	Nonchemo drug, separately paid list or no drug billed (subgroup Z)	Chemo drug, separately paid list (subgroup Y)	Admin APC	APC median	Applicable addenda
Q0081	X				A	$274.47	L
Q0081			X		B	107.93	M
Q0083		X			C	125.86	N
Q0083				X	D	39.10	O
Q0084		X			E	257.57	P
Q0084				X	F	149.38	Q

The payment policy is identical to the policy described in option 3 including the discount for Q0081 when billed with Q0083 and/or Q0084. Although this option would not require hospitals to change coding of drug administration it would, unlike options 2 and 3, require accurate coding of HCPCS codes for drugs in order to ensure proper payment. Additionally, we would revise the definitions of the administration codes to ''per day'' instead of ''per visit.''

Similar to option 3, we would make payment for up to three drug administrations per day, if appropriate. Where a code is billed with a packaged drug suitable for the code, we would pay the APC for the packaged drug. Where both a packaged drug and a

separately paid drug were administered via the same route of administration (and therefore only one code was billed), we would pay the APC only for the administration of the packaged drug and would pay separately for the separately paid drug and would not pay the APC for administration of the separately paid drug. In no case would we pay for more than one unit of an administration code.

Under options 2, 3, and 4, we would return a claim to the provider when a chemotherapy administration code was reported without a HCPCS code for a chemotherapy drug. Therefore, it is very important that commenters advise us as to whether there are any cancer chemotherapy drugs that are not included in Addenda L, M, N, O, P, or Q. Specifically, we solicit comments as to whether there are any cancer chemotherapy drugs that do not have HCPCS codes.

We do not propose payment amounts for this option because the budget neutrality scalar would be different under this proposal than under option 2 (which was used in the scalar and impact analysis). We solicit comment on each option described above.

General Billing Instructions

Any previous regulatory or sub-regulatory guidance notwithstanding, we propose to implement the following billing rules under any of the above payment options:

(1) Q0081 may not be used to bill separately for the hanging of a bag of solution for which the sole purpose is to administer chemotherapy drugs; that charge should be billed as part of the charge for Q0084 or Q0085.

(2) Q0081 may not be billed when it is an integral part of another procedure. In those cases, the charge for the procedure should reflect the costs of the infusion therapy, either as part of the charge for the HCPCS code or as a revenue code charge (for example, hydration or drug administration during a surgical procedure performed under general anesthesia).

(3) Q0081, Q0083, and Q0084 should not be used to bill for the administration of radiopharmaceuticals that are administered as part of diagnostic or therapeutic nuclear medicine procedures. In those cases, the radionucliide should be billed with the appropriate nuclear medicine HCPCS code.

(4) Q0081, Q0083, and Q0084 may not be used to report the transfusion of blood, platelets, or any other blood products. Those transfusions should be reported by use of the appropriate HCPCS code(s) in APC 0110.

5. Generic Drugs, and Radiopharmaceuticals

In general, hospital acquisition costs for drugs, biologicals, and radiopharmaceutical agents with generic competitors are lower than the acquisition costs for sole source or multi-source drugs. In order to ensure that Medicare recognizes these lower costs in a timely manner, we are proposing a new method of calculating payment amounts for drugs, biologicals, and radiopharmaceuticals that are separately paid under the OPPS and for which the Food and Drug Administration (FDA) has recently approved generic alternatives when we determine our claims data do not reflect the costs of the generic alternatives.

Because many hospitals have long term purchasing arrangements for drugs and radiopharmaceuticals, we believe that there is generally a 12-month lag between the time that generic items are made available and when our claims data will accurately reflect the costs associated with the availability of the generic alternative. Therefore, during the interval between FDA approval of a generic item and the time when we would reasonably expect claims data to reflect the cost of generic alternatives, we propose to adopt the following methodology to price the affected drugs, biologicals, and radiopharmaceuticals under the OPPS.

We would first identify items approved for generic availability by the FDA during the 6 months before the first day of the claims period we would use as the basis for an annual OPPS update. Where we determine that our claims data do not reflect the costs of generic alternatives for a separately payable drug, biological, or radiopharmaceutical, we propose to base our payment rate on 43 percent of the AWP for the drug, biological, or radiopharmaceutical. As described in the 2003 OPPS rule (67 FR 66768), the ratio of hospital acquisition cost, on average, to AWP for multisource drugs with generic competitors equals 0.43. We believe that using this ratio would allow us to appropriately calculate the costs that hospitals incur when purchasing generic drugs or radiopharmaceuticals. When we determine that our claims data accurately reflect the cost of the generic alternative(s), we would use the claims data to set payment rates in preference to 43 percent of AWP for the drug or radiopharmaceutical.

We considered another payment option where we would base our payment rate on the lower of: (1) The median cost (with dampening if applicable) based on claims data; or (2) the Federal Supply Schedule price. We are not proposing this policy because we believe we would not be able to calculate payment rates that are close to the actual hospital acquisition costs of generic alternatives since the Federal Supply Schedule represents prices that are lower than the prices paid by most hospitals. Also, median costs from the claims data would not reflect the actual cost of generics because of the time lag described above.

To apply this payment methodology to the 2004 OPPS update, we reviewed FDA approvals for generic drugs, biologicals, and radiopharmaceuticals issued between October 2001 and December 2002. We found six drugs, which we propose to be separately paid under the 2004 OPPS that had generic alternatives approved during that time. These drugs are: Daunorubicin, Bleomycin, Pamidronate, Paclitaxel, Ifosfomide, and Idarubicin. Table 21 shows the dates when the FDA approved generic alternatives for these drugs.

We understand that there is a wide range of utilization for these drugs in the OPPS and that price reductions for generic drugs will depend on their utilization and the types of illnesses for which they are used. However, we would not expect claims data from April 1, 2002 through December 31, 2002 to reflect fully the availability of the generic alternatives.

Table 21 shows the median cost for these six drugs as determined by claims data (with any adjustments for APCs that decreased in median cost by more than 15 percent from 2003 to 2004) and their costs at 43 percent of AWP as determined under the July 2003 update of the Medicare Single Drug Pricer.

We solicit comments on this proposed method of calculating payment for drugs, biologicals, and radiopharmaceuticals for which generic alternatives have recently been approved. Specifically, we are interested in comments concerning our proposed methodology for identifying these items, whether we properly identified all the items, and whether our proposed payment policy for these generic alternatives is appropriate.

TABLE 21.—PROPOSED LIST OF SEPARATELY PAYABLE OPPS DRUGS WITH GENERIC ALTERNATIVES APPROVED BETWEEN OCTOBER 2001 AND DECEMBER 2002

APC	Description	Date of Generic Approval by the FDA	43% of AWP	2004 Median cost (with dampening if applicable)
0832	Idarubicin hcl injection	May 2002	$190.08	$188.25
0831	Ifosfomide injection	May 2002	68.07	115.46
0863	Paclitaxel injection	May 2002	74.27	116.61
0730	Pamidronate disodium	May 2002	120.34	184.40
0857	Bleomycin sulfate injection	October 2001	130.98	169.28
0820	Daunorubicin hcl injection	November 2001	35.46	89.65

6. Orphan Drugs

In response to last year's proposed rule, many commenters explained that many orphan drugs were life-saving therapies used solely for the treatment of rare disorders where no other treatment was available. They further stated that many of these drugs would be received by very few Medicare beneficiaries and that if we packaged these drugs into other procedures, our payment rates would be insufficient to recognize their high cost, thus impairing the access of beneficiaries who needed the drugs. These commenters also stated that the claims data we used to set payment rates for 2003 did not accurately reflect the cost of these drugs. We shared these concerns, and in the November 1, 2002 final rule (67 FR 66772), we set forth the following payment policy:

We identified 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 condition(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). Payment for drugs that met these criteria was made outside of OPPS under reasonable cost.

In that same rule, we identified four orphan drugs (J0205 Injection, alglucerase, per 10 units; J0256 Injection, alpha 1-proteinase inhibitor, 10 mg; J9300 Gemtuzumab ozogamicin, 5 mg; and J1785 Injection, imiglucerase, per unit) as meeting these criteria. Therefore, we excluded them from payment under OPPS and paid for them at reasonable cost in 2003.

We received several comments in response to the final rule, stating that we had not identified all drugs that qualified for special payment as orphans under our criteria. After reviewing these comments, we have identified 7 additional drugs that meet our criteria. These drugs are: J2355 Injection, oprelvekin, 5 mg; J3240 Injection, thyrotropin alpha, 0.9 mg; J7513 Daclizumab parenteral, 25 mg; J9015 Aldesleukin, per vial; J9160 Denileukin diftitox, 300 mcg; J9216 Interferon, gamma 1–b, 3 million units; and Q2019 Injection, basiliximab, 20 mg.

We have now identified a total of 11 drugs that meet our orphan drug criteria, and we expect to identify more such drugs in the future. Last year's policy was intended to narrowly target a very small number of drugs received by very few Medicare beneficiaries in order to ensure beneficiary access to life saving therapies. The aggregate number of Medicare beneficiaries who will receive the 11 drugs that meet our criteria for orphans is significantly higher than the number who receive the 4 we identified last year. Furthermore, as we identify more drugs that meet our criteria, we expect the number of beneficiaries who receive these drugs to grow. As the number of beneficiaries who receive these drugs increases, so do total payments for the drugs. Therefore, we no longer believe that paying for these drugs at reasonable cost, outside of OPPS, is appropriate. Our goal is to pay for as many hospital outpatient department (OPD) services as possible under the OPPS system. We believe that any payments made outside of OPPS should remain relatively small and, as in the case of vaccines, be made because it is unlikely our claims data will reflect the cost of the item or service (see discussion of vaccines below).

In the case of orphan drugs, we believe that our claims data for April 1, 2002 through December 31, 2002 do reflect the cost of orphan drugs, and we are concerned about the potential of making ever increasing payments for these drugs outside of the OPPS. Furthermore, we believe that many of the concerns expressed by commenters would be addressed if we continue to make separate payment for these drugs.

Therefore, we propose the following payment policy for orphan drugs:

- We propose to continue using the same criteria to identify orphan drugs used solely for an orphan condition under the OPPS.
- We propose to discontinue retrospective cost payments and to make prospective payments under the OPPS for those identified orphan drugs.
- We propose to base payments on the same methodology we use to pay for other drugs including any limitation on payment reductions (as described above).
- We propose to make separate payment for orphan drugs and place them in APCs.

We solicit comment on each of these proposals and request that commenters submit information meeting the same criteria as comments for other drugs (as discussed above).

7. Vaccines

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 said 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 OPPS in 2002 are being paid at reasonable cost for these vaccines in 2003. We are aware that access concerns continue to exist for these vaccines; therefore, we propose to continue paying for influenza and pneumococcal pneumonia vaccines under reasonable cost methodology.

8. Blood and Blood Products

From the onset of the OPPS, we have made separate payment for blood and blood products in APCs rather than packaging them into payment for the procedures with which they were administered. As we explained in the April 7, 2000 final rule (65 FR 18449), wide variations in patient requirements convinced us that we should pay for these items separately rather than packaging their costs into the procedural APCs. Moreover, the Secretary's Advisory Council on Blood Safety and Access recommended that blood and blood products be paid separately to ensure that we did not create any incentives that were inconsistent with the promotion of blood safety and access. Therefore, we propose to continue to pay separately for blood and blood products.

As described in the November 1, 2002 final rule (67 FR 66773), we applied a special dampening option to blood and blood products that had significant reductions in payment rates from 2002 to 2003. For 2003, we limited the decrease in payment rates for blood and blood products to approximately 15 percent.

After careful comparison of the 2003 dampened medians with the 2004 medians from our claims data, we believe that establishing payment rates based on the 2004 median costs would, for many blood and blood products, result in payments that are significantly lower than hospital acquisition costs. In order to mitigate any significant payment reductions and to minimize any compromise in access of beneficiaries to these products, we propose to limit the decrease in payment rates for blood and blood products from 2003 to 2004 by approximately 10 percent.

This is different than the amount by which we limited payment decreases last year because when we applied the dampening methodology used for the 2003 OPPS to blood and blood products, we observed that it did not sufficiently limit payment reductions for the blood and blood products with large decreases in median cost from 2003 to 2004. Therefore, we are proposing for 2004 a variation of the methodology used for the 2003 OPPS because we believe that a 10 percent limit in the decrease in payment rates for blood and blood products would better reflect hospital acquisition costs, ensure appropriate reimbursement to hospitals, and enable continued beneficiary access to blood and blood products.

The list of APCs containing blood and blood products can be found in the November 1, 2002 final rule (67 FR 66750). We note that the APCs for these products are intended to make payment for the costs of the products. Costs for storage and other administrative expenses are packaged into the APCs for the procedures with which the products are used.

We solicit comment on this proposal especially from hospitals. We are especially interested in comments that include verifiable information about the widely available acquisition cost of commonly used blood and blood products.

9. Intravenous Immune Globulin

Following publication of the proposed rule on August 9, 2002, we received comments urging us to reclassify intravenous immune globulin (IVIG) as a blood product. After carefully reviewing these comments with our medical advisors, we decided to make final our proposal to classify immune globulin as a biological, subject to the same payment policy we implemented for other drugs and biologicals. Our reasons were set forth in the November 1, 2002 final rule (67 FR 66774). Since implementation of the 2003 OPPS update, we have received further comments on this decision. These commenters continue to assert that we should make special payment provisions for IVIG and reclassify IVIG as a blood and blood product. They have expressed particular concern about the potentially negative impact of our payment policy for IVIG on patient access, especially for those individuals who have primary immune deficiency diseases.

We appreciate the concerns regarding our decision to pay for IVIG in accordance with the payment methodology we applied to other drugs and biologicals in the 2003 update of the OPPS. We have reviewed the claims data that are the basis for the payment rates in this proposed rule, and our analysis reveals that IVIG would be separately payable in 2004. The claims data for IVIG are robust, and the most recent claims data, when compared with claims data used in earlier updates of the OPPS suggest that hospital costs are consistent and that hospitals are billing accurately for these products. Therefore, we believe that payment for these products is appropriate using the methodology we propose to implement for other drugs and biologicals. Therefore, we propose to continue to classify IVIG as a biologic. We solicit comments on this proposal.

10. Drug and Device Coding

We propose to require hospitals to report individual codes for all drugs and devices used during the episode, including those that are packaged.

Last year (CY 2003), the pass-through status of many drugs and devices expired. These drugs and devices were packaged, consistent with the fundamental principles of a prospective payment system. By packaging the costs of items and services into the payment for the primary procedure or service with which they are associated, we encourage hospital efficiency and provide hospitals with the ability to manage their resources with maximum flexibility. We believed that an additional advantage of increased packaging would be that hospitals would no longer need to report codes for the individual items and services included in the package. While we continue to support packaging to the greatest extent possible, the loss of coding information on claims creates some obstacles to accurate rate-setting.

The data for 2002 that we are using for CY 2004 rate-setting still have considerable drug and device coding information. However, for the CY 2005 OPPS update, for which 2003 data would be used, there will be much less information regarding specific drug and device costs. We do not expect to have as much Medicare claims information on which to base certain decisions such as which drugs to remove from packaged status and pay separately.

This concerns us and has led us to consider the need for drug and device coding. Even though payment is not directly related to that information, we believe that reporting the codes may be in hospitals' best interest because it may result in the most accurate payments. For example, in setting the weights of certain device-related APCs, we discovered that the median costs of those APCs were higher when we used only claims on which the device codes appeared. Similarly, certain drug administration APCs have higher median costs when separate HCPCS for drugs are reported on the claims.

If we are to continue to price drugs and devices using up-to-date median costs from claims data, we need information on the costs of the items, even when packaged. We propose to require the separate coding of individual drugs and device categories,

even where their costs are packaged, to address this need. We would like comments on whether or not to require coding of devices. We also solicit comments regarding our proposal to report drug codes on claims and alternative methods for rate-setting if codes for drugs and/or devices are no longer present on the claims. We are particularly interested in receiving comments from hospitals on this proposal.

11. Payment for Split Unit of Blood

Since implementation of the OPPS, we have assigned status indicator ''E'' to HCPCS code P9011, blood (split unit). Status indicator ''E'' designates services for which payment is not allowed under the OPPS or services that are not covered by Medicare. P9011 was created to identify situations where one unit of red blood cells or whole blood, for example, is split and half of the unit is transfused to one patient and the other half to another patient. Because use of split units is not uncommon, we propose to change the status indicator for P9011 from ''E'' to ''K'' and assign it to a blood and blood product APC that pays approximately 50 percent of the payment for the whole unit of blood. We propose to assign P9010 to APC 0957 (Platelet concentrate) with a payment rate of $37.30. We invite comments on this proposed change in the status indicator and payment amount for P9010.

12. Other Issues

We propose to continue our payment policy for Procrit and Aranesp for calendar year 2004. As explained in detail in the November 1, 2002 final rule (67 FR 66758), Aranesp and Procrit are in separate APCs, and are paid at equivalent rates with the application of a ratio to convert the dosage units of Aranesp into units of Procrit. The current conversion ratio is based on the best information available at the time we developed the final rule for calendar year 2003. In the final rule, we explained that we based our conclusion regarding the appropriate conversion ratio on the FDA labeling for each product and the body of available clinical evidence contained in published and unpublished articles and abstracts and in materials provided by the products' manufacturers. We indicated that we might refine the conversion ratio as soon as feasible based on information not available at the time we established the current conversion ratio.

Consistent with our statements in the final rule, we have continued to gather information regarding an appropriate conversion ratio by reviewing recent published studies and data from alternative sources. We have met with the manufacturers of the products and consulted with clinicians. We are continuing to evaluate this additional data and information. However, we have not yet determined whether the data would support a change to the current policy. We remain open to establishing a different conversion ratio in the final rule if we conclude that a change is warranted based on public comments and information submitted during the public comment period and/or any other information we consider in developing the final rule.

Therefore, we propose to continue with the current policy regarding payment for Procrit and Aranesp, including the current conversion ratio. We solicit comments on this issue and are especially interested in submission of articles in peer-reviewed publications and other clinical data concerning the frequency of administration and the dosage amounts of these agents. Submission of prospective, randomized, controlled trials comparing the dosage amounts, frequency of administration, and clinical outcomes of these agents are preferred. All data submitted would be available to the public. We would base any changes to our current payment policy for these two drugs only on data that we could make available to the public.

VII. Wage Index Changes for CY 2004

Section 1833(t)(2)(D) of the Act requires that we determine a wage adjustment factor to adjust for geographic wage differences, in a budget neutral manner, that portion of the OPPS payment rate and copayment amount that is attributable to labor and labor-related costs.

We used the proposed Federal fiscal year (FY) 2004 hospital inpatient PPS wage index to make wage adjustments in determining the proposed payment rates set forth in this proposed rule. The proposed FY 2004 hospital inpatient wage index published in the May 19, 2003 **Federal Register** (68 FR 27154) is reprinted in this proposed rule as Addendum H—Wage Index for Urban Areas; Addendum I—Wage Index for Rural Areas; and Addendum J—Wage Index for Hospitals That Are Reclassified. We propose to use the final FY 2004 hospital inpatient wage index to calculate the payment rates and coinsurance amounts that we will publish in the final rule implementing the OPPS for CY 2004.

VIII. Copayment for CY 2004

In the November 30, 2001 final rule (66 FR 59887), we adopted a methodology that applied five rules for calculating APC copayment amounts when payments for APC groups change because the APCs' relative weights are recalibrated or when individual services are reclassified from one APC group to another. In calculating the unadjusted copayment amounts for 2004, we encountered circumstances that the methodology in the November 30, 2001 final rule either did not address or whose applicability was ambiguous. For example, rules 2 and 3 refer to payment rate changes resulting from the recalibration of relative payment weights but do not clearly apply to payment rate changes resulting from the reclassification of HCPCS codes from one APC group to another APC group. Therefore, we propose to revise and clarify the methodology we would follow to calculate unadjusted copayment amounts, including situations in which recalibration of the relative payment weight of an existing APC results in a change in the APC payment; to situations in which reclassification of HCPCS codes from an existing APC to another APC results in a change in the APC payment; and to payment rates for newly created APCs that are comprised of HCPCS codes from existing APCs.

As a general rule, we would seek to lower the coinsurance rate for the services in an APC from the prior year. This principle is consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services and with section 1833(t)(3)(B), which indicates the congressional goal of achieving 20 percent coinsurance when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts to new services. However, in no event is the proposed 2004 coinsurance rate for an APC group lower than 20 percent or greater than 50 percent of the payment rate.

We propose to determine copayment amounts in 2004 and subsequent years in accordance with the following rules.

1. When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.

2. If a new APC that did not exist during the prior year is created and

consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.

3. If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance rate is less than 20 percent).

4. If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.

5. If HCPCS codes are added to or deleted from an APC, and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).

6. If HCPCS codes are added to an APC, and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance rate of the codes being added to the reconfigured APC.

This methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or the recalibration of relative payment weights.

IX. Conversion Factor Update for CY 2004

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 2004, 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 2004 published in the inpatient PPS proposed rule on May 19, 2003 is 3.5 percent. To set the proposed OPPS conversion factor for 2004, we increased the 2003 conversion factor of $52.151 (the figure from the November 1, 2002 final rule (67 FR 66788) by 3.5 percent.

In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the proposed conversion factor for 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 budget neutrality factor of 1.003 for wage index changes by comparing total payments from our simulation model using the proposed FY 2004 hospital inpatient PPS wage index values to those payments using the current (FY 2003) wage index values. In addition, for CY 2004, allowed pass-through payments have decreased to 2 percent of total OPPS payments, down from 2.3 percent in CY 2003. The 0.3 percent was also used to adjust the conversion factor.

The increase factor of 3.5 percent for 2004, the required wage index budget neutrality adjustment of approximately 1.003, and the 0.3 percent adjustment to the pass-through estimate, result in a proposed conversion factor for 2004 of 54.289.

X. Proposed Outlier Policy and Elimination of Transitional Corridor Payments for CY 2004

A. Proposed Outlier Policy for CY 2004

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, 59888), we specified that beginning with 2002, we will 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 outliers on a service-by-service basis.

As explained in the April 7, 2000 final rule (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 propose to continue to set the target for outlier payments at 2.0 percent, as we did for CYs 2001, 2002, and 2003. For 2003, the outlier threshold is met when costs of furnishing a service or procedure exceed 2.75 times the APC payment amount, and the current outlier payment percentage is 45 percent of the amount of costs in excess of the threshold. For the reasons discussed in detail in section XI.E of this preamble, we are proposing to establish two separate outlier thresholds, one for community mental health centers (CMHCs) and one for hospitals. For CY 2004, we propose to continue to set the target for outlier payments at 2.0 percent of total OPPS payments (a portion of that 2.0 percent, 0.36 percent, would be allocated to CMHCs for PHP services). Based on our simulations for 2004, we propose to set the hospital threshold for 2004 at 2.75 times the APC payment amount, and the proposed 2004 payment percentage applicable to costs over the threshold at 50 percent. We propose to set the threshold for CMHCs for 2004 at 11.75 times the APC payment amount and the 2004 outlier payment percentage applicable to costs over the threshold at 50 percent.

B. Elimination of Transitional Corridor Payments for CY 2004

Since the inception of the OPPS, providers have been eligible to receive additional transitional payments if the payments they received under the OPPS were less than the payments they would have received for the same services under the payment system in effect before the OPPS. Under 1833(t)(7) of the Act, most hospitals that realize lower payments under the OPPS received transitional corridor payments based on a percent of the decrease in payments. However, rural hospitals having 100 or fewer beds, as well as cancer hospitals and children's hospitals described in section 1886(d)(1)(B)(iii) and (v) of the Act, were held harmless under this provision and paid the full amount of the decrease in payments under the OPPS. Transitional corridor payments were intended to be temporary payments to ease providers' transition from the prior cost-based payment system to the prospective payment system. Beginning January 1, 2004, in accordance with section 1833(t)(7) of the Act, transitional corridor payments will no longer be paid to providers other than cancer hospitals and children's hospitals. Cancer hospitals and children's hospitals are held harmless permanently under the transitional corridor provisions of the statute.

We are concerned that small rural hospitals are not able to achieve the same level of operating efficiencies as larger rural hospitals and urban hospitals, and we are concerned that the decrease in payments these hospitals may experience once they stop receiving transitional corridor payments will result in these hospitals having to decrease or altogether cease to provide certain outpatient services. A reduction of services could have consequences for Medicare beneficiaries and their continued access to care in rural areas.

In light of these concerns, one thing we could do is to provide increased APC payments for clinic and emergency room visits furnished by rural hospitals having 100 or fewer beds. Any adjustment to payments for these hospitals would be made under the authority granted to the Secretary under section 1833(t)(2)(E) of the Act, to establish in a budget neutral manner adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals. We invite comments on whether we should provide an adjustment, such as the one described above, for small rural hospitals.

XI. Other Policy Decisions and Proposed Changes

A. Hospital Coding for Evaluation and Management (E/M) Services

Facilities code clinic and emergency department visits using the same [Physicians'] Current Procedural Terminology (CPT) codes as physicians. For both clinic and emergency department visits, there are currently five levels of care. Because these codes were defined to reflect only the activities of physicians, they are inadequate to describe the range and mix of services provided to patients in the clinic and emergency department settings (for example, ongoing nursing care, preparation for diagnostic tests, and patient education). An example to illustrate the services that are billed using E/M codes in the hospital outpatient department follows:

An adult male patient presents to a clinic after a fall while working in his yard. As a result, he has scraped off the top layer of skin covering his entire back. The physician examines the patient, finds a dirty and possibly infected wound, which is the only injury. The physician orders the nurse to clean the wound, apply antiseptic medication, and dress the wound. In addition, the physician orders an intramuscular antibiotic and a tetanus injection.

The nurse will spend a considerable amount of time cleaning and dressing the wound with large amounts of sterile supplies (because of the large body surface area) as well as administering medications. The nurse also will give the patient discharge instructions regarding the care of the wound.

Although the physician services are captured using existing E/M codes, the additional staff and supplies integral to the outpatient department services are not. The low level E/M code that describes the physician services in the example is not reflective of the services provided by the nurse (and any other staff that may have become involved) or of the quantity of supplies used in the treatment.

In the April 7, 2000 final rule (65 FR 18434), we stated that in order to ensure proper payment to hospitals, it was important that emergency and clinic visits be coded properly. To facilitate proper coding, we required each hospital to create an internal set of guidelines to determine what level of visit to report for each patient. In the August 24, 2001 proposed rule (66 FR 44672), we asked for public comments regarding national guidelines for hospital coding of emergency and clinic visits. Commenters recommended that we should keep the current E/M coding system until facility specific E/M 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, implement, and that are compliant with the Health Insurance Portability and Accountability Act (HIPAA) requirements.

APC Panel Recommendations

During its January 2002 meeting, the APC Panel made the following recommendations regarding coding for evaluation and management services:

1. Propose, and make final, facility coding guidelines for E/M services for CY 2004.
2. Create a series of G codes with appropriate descriptors for facility E/M services.
3. Maintain a single set of codes, with five levels of service, for emergency department visits.
4. Develop a single set of codes, with five levels of service, for clinic visits. The Panel specifically recommended that we not differentiate among visit types (for example, new, established, and consultation visits) for the purposes of facility coding of clinic visits.
5. Adopt the American College of Emergency Physicians (ACEP) facility coding guidelines as the national guidelines for facility coding of emergency department visits.
6. Develop guidelines for clinic visits that are modeled on the ACEP guidelines but are appropriate for clinic visits.
7. Implement these guidelines as interim and continue to work with appropriate organizations and stakeholders to develop final guidelines.

After careful review and consideration of written comments, oral testimony, and the APC Panel's recommendations, we proposed the following in the August 9, 2002 proposed rule (for implementation no earlier than January 2004):

1. To develop five G codes to describe emergency department services:
   GXXX1—Level 1 Facility Emergency Services;
   GXXX2—Level 2 Facility Emergency Services;
   GXXX3—Level 3 Facility Emergency Services;
   GXXX4—Level 4 Facility Emergency Services; and
   GXXX5—Level 5 Facility Emergency Services.
2. To develop five G codes to describe clinic services:
   GXXX6—Level 1 Facility Clinic Services;
   GXXX7—Level 2 Facility Clinic Services;
   GXXX8—Level 3 Facility Clinic Services;
   GXXX9—Level 4 Facility Clinic Services; and
   GXXX10—Level 5 Facility Clinic Services.
3. To replace CPT Visit Codes with the 10 new G codes for OPPS payment purposes.
4. To establish separate documentation guidelines for emergency visits and clinic visits.

In our November 1, 2002 final rule (67 FR 66792), we stated that the most appropriate forum for development of new code definitions and guidelines would be an independent expert panel that would make recommendations to us. We wanted to ensure that definitions and guidelines were developed using an open process involving a variety of experts in the field. We stated that it is critically important to the development, acceptance, and implementation of facility visit code definitions and guidelines that the organizations that develop the guidelines also maintain and update the guidelines and provide ongoing education to providers on use of the codes. In light of the expertise of organizations such as the American Hospital Association (AHA) and the American Health Information Management Association (AHIMA), we felt that these organizations were particularly well equipped to make recommendations to us and to provide ongoing education to providers. Furthermore, we stated that the process should provide adequate time for the education of clinicians and coders and for hospitals to make the necessary changes in their systems to accommodate the new codes and guidelines.

On their own initiative, the AHA and the AHIMA convened an independent expert panel of individuals from various

organizations to develop code descriptions and guidelines for hospital emergency department and clinic visits and make recommendations to us.

The panel recommended the following to us.

1. We should make payment for emergency and clinic visits based on four levels of care.

2. We should create HCPCS codes to describe these levels of care as follows:

GXXX1—Level 1 Emergency Visit.
GXXX2—Level 2 Emergency Visit.
GXXX3—Level 3 Emergency Visit.
GXXX4—Critical Care provided in the emergency department.
GXXX5—Level 1 Clinic Visit.
GXXX6—Level 2 Clinic Visit.
GXXX7—Level 3 Clinic Visit.
GXXX8—Critical Care provided in the clinic.

3. We should replace all the HCPCS currently in APCs 600, 601, 602, 610, 611, 612, and 620 with GXXX1 through GXXX8.

4. Based on the above recommendations, we would crosswalk payments as follows: GXXX1 to APC 610, GXXX2 to APC 611, GXXX3 to APC 612, GXXX4 to APC 620, GXXX5 to APC 600, GXXX6 to APC 601, GXXX7 to APC 602, and GXXX8 to APC 620. These crosswalks and code descriptions are listed in Table 22 below.

TABLE 22.—CROSSWALKS OF 2003 HCPCS CODES TO THE PROPOSED G CODES

2003 HCPCS description	2004 G code description	2003 HCPCS	2004 Proposed G codes	APC	Payment amount
Emergency department visit	Level 1 Emergency Visit	99281 99282	GXXX1	0610	$76.80
Emergency department visit	Level 2 Emergency Visit	99283	GXXX2	0611	$135.08
Emergency department visit	Level 3 Emergency Visit	99284 99285	GXXX3	0612	$234.72
Critical care	Level 4 Critical Care provided in the emergency department.	99291 99292	GXXX4	0620	$503.03
Office/outpatient visit, new	Level 1 Clinic Visit	99201 99202	GXXX5	0600	$50.90
Office/outpatient visit, new	Level 2 Clinic Visit	99203	GXXX6	0601	$54.46
Office/outpatient visit, new	Level 3 Clinic Visit	99204 99205	GXXX7	0602	$84.71
Office/outpatient visit, established	Level 1 Clinic Visit	99211 99212	GXXX5	0600	$50.90
Office/outpatient visit, established	Level 2 Clinic Visit	99213	GXXX6	0601	$54.46
Office/outpatient visit, established	Level 3 Clinic Visit	99214 99215	GXXX7	0602	$84.71
Office consultation	Level 1 Clinic Visit	99241 99242	GXXX5	0600	$50.90
Office consultation	Level 2 Clinic Visit	99243	GXXX6	0601	$54.46
Office consultation	Level 3 Clinic Visit	99244 99245	GXXX7	0602	$84.71
Critical care	Level 4 Critical Care provided in the clinic.	99291 99292	GXXX8	0620	$503.03

The independent panel convened by the AHA and AHIMA recommended these levels in anticipation of the development of national coding guidelines for emergency and clinic visits that meet the following criteria we announced in the August 9, 2002 proposed rule (67 FR 52131):

1. Coding guidelines for emergency and clinic visits should be based on emergency department or clinic facility resource use, rather than physician resource use.

2. Coding guidelines should be clear, facilitate accurate payment, be usable for compliance purposes and audits, and comply with HIPAA.

3. Coding guidelines should only require documentation that is clinically necessary for patient care. Preferably, coding guidelines should be based on current hospital documentation requirements.

4. Coding guidelines should not create incentives for inappropriate coding (for example, up-coding).

We have received recommendations for a set of coding guidelines from the independent E/M panel comprised of members of the AHA and AHIMA. We propose to implement new evaluation and management codes only when we are also ready to implement guidelines for their use, after allowing ample opportunity for public comment, systems change, and provider education. We also propose to use cost data from the current HCPCS codes in these APCs to determine the relative weights of these APCs until cost data from GXXX1 through GXXX8 are available to set relative weights. We note that this proposal requires discontinuing the use of all HCPCS codes in these APCs and would not allow us to collect cost data for the five levels of emergency and clinic visits that are currently described by CPT codes. We further note that we would no longer be able to distinguish among the costs for visits by new patients, established patients, consultation patients, or patients being seen for more specialized care (for example, pelvic screening exams and glaucoma screening exams).

We would be using claims data from current HCPCS codes and crosswalking those data to the new codes in the same APCs; therefore, there would be no change in payment for any of these services as a result of these coding changes. Once cost data become available from the new HCPCS codes, we would use those data to set the relative weights, and, therefore, there should be no budgetary impact.

We are currently considering the set of proposed national coding guidelines for emergency and clinic visits recommended by the independent panel. We plan to make any proposed guidelines available to the public for comment on the OPPS Web site as soon as they are complete. We will notify the public through our listserve when these proposed guidelines become available. To subscribe to this listserve, please go to the following Web site: *http://www.cms.hhs.gov/medlearn/listserv.asp* and follow the directions to the OPPS

listserve. With regard to the development of these guidelines, our primary concerns are—

1. To make appropriate payment for medically necessary care;
2. To minimize the information collection and reporting burden on facilities;
3. To minimize any incentives to provide unnecessary or low quality care;
4. To minimize the extent to which separately billable services are counted as E/M services;
5. To develop coding guidelines that are consistent with facility resource use; and
6. To develop coding guidelines that are clear, facilitate accurate payment, are useful for compliance purposes and audits, and comply with HIPAA. Before implementation of the codes and coding guidelines, adequate time will be provided for the education of clinicians and coders and for hospitals to make the necessary changes in their systems to accommodate the codes and guidelines. We are requesting comments on the amount of time hospitals believe would be adequate to implement these new codes and guidelines. We remain committed to working with appropriate organizations and stakeholders in our continuing development of a standard set of codes and national guidelines for facility coding of emergency and clinic visits.

B. Status Indicators and Issues Related to OCE Editing

The status indicators we assign to HCPCS codes and APCs under the OPPS have an important role in 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. We are providing our proposed status indicator (SI) assignments for APCs in Addendum A, HCPCS codes in Addendum B, and definitions of the status indicators in Addendum D.

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 which HCPCS codes 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 D defines the meaning of each status indicator for purposes of the OPPS.

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, in 2004 we propose to use the status indicators in the following manner:

- We use ''A'' to indicate services that are paid under some payment method other than OPPS, such as 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 D.
- We use ''C'' to indicate inpatient services that are not payable under the OPPS.
- We use ''D'' to indicate a code that was deleted effective with the beginning of the calendar year.
- We use ''E'' to indicate services for which payment is not allowed under the OPPS or that are not covered by Medicare.
- We use ''F'' to indicate acquisition of corneal tissue, which is paid at reasonable cost. (In 2003, we also use ''F'' to indicate those orphan drugs that are paid at reasonable cost.) In 2004, we propose to revise the definition of ''F'' solely to indicate acquisition of corneal tissue paid at reasonable cost.
- We use ''G'' to indicate drugs and biologicals that are paid under OPPS transitional pass-through rules.
- We use ''H'' to indicate devices that are paid under OPPS transitional pass-through rules.
- We use ''K'' to indicate drugs, biologicals (including blood and blood products), radiopharmaceutical agents, and certain brachytherapy seeds that are paid in separate APCs under the OPPS but that are not paid under OPPS transitional pass-through rules.
- We use ''L'' to indicate flu and pneumococcal immunizations which are paid at reasonable cost but to which no coinsurance or copayment apply.
- We use ''N'' to indicate services that are paid under the OPPS but for which payment is packaged into another service or APC group.
- We use ''P'' to indicate services that are paid under the OPPS but only in partial hospitalization programs.
- We use ''S'' to indicate significant procedures that are paid under OPPS but to which the multiple procedure reduction does not apply.
- We use ''T'' to indicate significant services that are paid under the OPPS and to which the multiple procedure payment discount under OPPS applies.
- We use ''V'' to indicate medical visits (including clinic or emergency department visits) that are paid under the OPPS.
- We use ''X'' to indicate ancillary services that are paid under the OPPS.

The software that controls Medicare payment looks to the status indicators attached to the HCPCS codes and APCs for direction in the processing of the claim. Therefore, the assignment of the status indicators has significance for the payment of services.

We are proposing the status indicators identified 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.

C. Observation Services

In the November 1, 2002 update to the OPPS (67 FR 66794), we summarized and clarified previously published guidance (Transmittal A–02–026) regarding payment requirements for HCPCS code G0244, Observation care provided by a facility to a patient with congestive heart failure, chest pain or asthma, minimum of 8 hours, maximum 48 hours. We also implemented HCPCS codes G0263 and G0264 to identify patients directly admitted to observation. In January 2003, we published Transmittal A–02–129, which provides further instructions regarding billing for observation services. In this proposed rule, we are neither proposing anything new with regard to observation services, nor are we seeking public comment on observation issues at this time. As we have in the past, we will update by Program Memorandum any changes in the list of ICD–9–CM codes required for payment of HCPCS code G0244 resulting from October 1 annual update of ICD–9–CM. Any such changes will be included in the 2004 final OPPS rule with comment period and the public will have an opportunity to comment at that time.

D. Procedures That Will Be Paid Only as Inpatient Procedures

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, 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 and the November 30, 2001 final rules, 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, 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 ambulatory surgical center (ASC) procedures or proposed by us for addition to the ASC list.

At its January 2003 meeting, the APC Panel did not make recommendations regarding procedures on the inpatient list, and we are not proposing to make any of the procedures that are currently on the inpatient list in Addendum E payable under the OPPS in 2004. We solicit comments on whether any procedures in Addendum E should be paid under the OPPS. We ask commenters recommending reclassification of a procedure 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 also solicit comments on the appropriate APC assignment for the procedure in the event that we determine in the final rule, based on comments, that the procedure would be payable under the OPPS in 2004.

Following our review of any comments that we receive about the procedures in Addendum E, we propose either to assign a CPT code to an APC for payment under the OPPS or, if the comments do not provide sufficient information and data to enable us to make a decision, to present the comments to the APC Panel at its 2004 meeting.

Proposed New APC To Pay for Services Furnished on Same Date as Service with Modifier –CA:

In the 2003 update of the OPPS, we implemented a new modifier –CA, Procedure payable only in the inpatient setting when performed emergently on an outpatient who dies before admission. In section VI of Transmittal A–02–129, issued on January 3, 2003, we instructed hospitals on the use of modifier –CA when submitting a claim on bill type 13x for a procedure that is on the inpatient list and that is assigned payment status indicator ''C.'' (Transmittal A–02–129 can be found on our Web site at *cms.hhs.gov*.) We also implemented in the November 1, 2002 final rule (67 FR 66799) a new payment policy to allow payment, under certain conditions, for outpatient services on a claim that have the same date of service as the HCPCS code billed with modifier –CA. A single payment for outpatient services on the claim, other than those coded with status indicator ''C'' and modifier –CA, is currently made under APC 977.

We reviewed this policy and determined that assigning payment for these services to APC 977, which is a New Technology APC, is problematic because payment under New Technology APCs is a fixed amount that does not have a relative payment weight and is, therefore, not subject to recalibration based on hospital costs. We propose to establish a new APC for which payment would be made under certain conditions 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 who dies before admission to the hospital as an inpatient. Beginning in 2004, hospitals would be paid under APC 375 instead of APC 977 for services furnished on the same date of service that a procedure with status indicator ''C'' and modifier –CA is billed. We propose at the outset to set the payment rate for APC 375 in the amount of $1,150, which is the payment amount for the newly structured New Technology APC that would replace APC 977. When the APC weights are recalibrated in 2005, we would use charge data from CY 2003 claims for line items that have the same date of service as the line with modifier –CA and that show a HCPCS code with status indicator ''V,'' ''S,'' ''T,'' ''X,'' ''N,'' or ''K'' to calculate a median cost and relative payment weight for APC 375. Once we have claims data, we would be able to determine whether it is appropriate to calculate a relative payment weight based on median costs from our claims data or to continue a fixed payment rate for these special cases. We invite comments on these proposed changes.

E. Partial Hospitalization Payment Methodology

1. Background

As we discussed in the April 7, 2000 OPPS final rule (65 FR 18452), partial hospitalization is an intensive outpatient program of psychiatric services provided to patients in place of inpatient psychiatric care. A partial hospitalization program (PHP) may be provided by a hospital to its outpatients or by a Medicare-certified community mental health center (CMHC). 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.

The PHP per diem amount was based solely on hospital data. Section 1833(t)(2)(C) of the Act required that we initially establish relative payment weights based on median (or mean, at the discretion of the Secretary) hospital costs determined by 1996 claims and cost report data. We analyzed the service components billed by hospitals over the course of a billing period and determined the median hospital cost of furnishing a day of partial hospitalization. The analysis of hospital partial hospitalization claims resulted in a per diem payment of $202.19, effective August 1, 2000. This amount was updated effective January 1, 2001 and April 1, 2002 to $206.82 and $212.27, respectively.

Although we did not use CMHC data in establishing the initial APC amount

for partial hospitalization, in the April 7, 2000 final rule, we committed to analyzing future data from hospitals and CMHCs to determine whether refinements to the per diem were warranted. As a result, for payment rates presented in the proposed and final rules in 2002, we used data from both hospitals and CMHCs to compute the CY 2003 per diem rate. A description of the methodology we followed in developing the CY 2003 PHP payment rate is presented below.

We based the CY 2003 per diem amount on hospital and CMHC claims data for services furnished from April 1, 2001 through March 31, 2002. We used data from all the hospital bills reporting condition code 41, which identifies the claim as partial hospitalization, and all bills from CMHCs, since 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. Unlike hospitals, CMHCs do not file cost reports electronically and the cost report information is not included in the Hospital Cost Report Information System (HCRIS). The CMHC cost reports are held by the Medicare fiscal intermediaries (FIs). As a result, we requested that the FIs forward to us the most recently available CMHC cost-to-charge ratios so that we could apply the ratio to the CMHC's billed charges and approximate the CMHC's per diem cost for PHP.

Per diem costs are computed by summing the line item costs on each bill and dividing by the number of days on the bill. Using this method of computing costs, preliminary per diem cost estimates for CMHCs were much higher than expected, in many cases more than twice the average per diem for *inpatient* psychiatric care. Closer examination of the CMHC cost report data summaries showed that costs from CMHC settled cost reports were considerably lower than costs from ''as submitted'' CMHC cost reports. To account for the difference between settled and as submitted cost report data, we computed the ratio of total settled costs to total as submitted costs over a 3-year period (CMHC FYs 1998 through 2000) and calculated an average adjustment factor (0.583), which we applied to the costs on each claim. As stated in the 2002 proposed and final OPPS rules, we thought that an adjustment factor of 0.583 was adequate to account for the difference between settled and ''as submitted'' CMHC cost reports and was more reflective of CMHC costs for PHP. However, we did not have an opportunity to examine the data in depth before publishing the OPPS final rule on November 1, 2002.

The adjusted CMHC per diem costs on each claim were summed, then divided by the number of days on the claim. We then combined the CMHC and hospital PHP data files and determined the median per diem cost for PHP. Effective January 1, 2003, the PHP APC amount was $240.03, of which $48.17 is the beneficiary's coinsurance.

2. PHP APC Update for CY 2004

For CY 2004, we analyzed hospital and CMHC PHP claims for services furnished between April 1, 2002 and December 31, 2002. We intended to propose to use the same methodology for computing median costs per day for CY 2004, including the adjustment factor, as we used to compute the CY 2003 PHP median cost per day. However, when we applied the adjustment factor to the CMHC claims to compute the CY 2004 per diem, the CMHC median cost per day was determined to be $605. Without the adjustment, the median cost per day for CMHCs to provide partial hospitalization services is $1,038. The median cost per day for hospital outpatient departments to provide the same benefit is $225. We do not believe it is reasonable for CMHCs to incur costs that are more than double those incurred by hospital outpatient departments providing PHP services. In addition, the median CMHC cost for a day of outpatient PHP services exceeds the average per diem cost for *inpatient* psychiatric facilities, which provide a full 24 hours of care, medications, and other ancillary services. We do not believe it is appropriate for Medicare to pay more for a day of outpatient treatment than for a day of inpatient psychiatric care.

In addition to the vast difference in median costs between CMHCs and hospital outpatient departments, we are concerned that this difference has grown significantly larger since last year. The median per diem cost for hospitals is about the same for 2003 and 2004 ($224 for CY 2003 compared to $225 for the proposed CY 2004 update), while the median per diem cost for CMHCs (after adjustment) has increased by 58 percent ($384 for CY 2003 compared to $605 for the proposed CY 2004 update). We believe that the increase in the median CMHC per diem cost is primarily due to large increases in CMHC charges, coupled with the application of outdated cost-to-charge ratios to determine the per diem cost. In a Program Memorandum issued on January 17, 2003 (Transmittal A–03–004), we directed FIs to recalculate hospital and CMHC cost-to-charge ratios using the most recently settled or tentatively settled cost reports by April 30, 2003. However, we did not receive the updated CMHC cost-to-charge ratios in time to use in our data analysis for this proposed rule.

Therefore, we are proposing a per diem rate for PHP services furnished during CY 2004 based solely on hospital PHP data. The resulting PHP APC 0033 amount, after scaling, is $208.95, of which $41.69 is the beneficiary's coinsurance. We are not inclined to use the CMHC data in computing the per diem amount until the data discrepancies can be more fully resolved. We anticipate receipt of the revised CMHC cost-to-charge ratios this summer and will analyze the updated CMHC cost data. To the extent we believe the updated cost-to-charge ratios result in a more reasonable median per diem rate, we propose to use the CMHC data in developing the final rate for CY 2004.

3. Outlier Payments to CMHCs

In a related matter, the use of outdated cost-to-charge ratios applied to current charges has resulted in an excessive amount of outlier payments being made to CMHCs. As a result of more in-depth analysis of the 2001 data files that were used to compute the CY 2003 PHP per diem amount, we discovered a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP. Of the approximately 660 hospital programs with claims for PHP in CY 2001, 25 hospitals received approximately $9,000 in outlier payments. By contrast, almost half of the 155 CMHCs in our CY 2001 data file were paid outlier payments, totaling approximately $48 million.

Based on preliminary analysis of the 125 CMHCs with claims in the CY 2002 data files, that is, April 1, 2002 through December 31, 2002, we have determined that CMHCs received approximately $37 million in outlier payments, compared to approximately $13,000 for all hospitals in the PHP data file. The $37 million in outlier payments to CMHCs almost equals the total amount paid to CMHCs in regular APC payments.

CMHCs have indicated that they are unable to reduce their costs to the per diem payment amount and that outlier payments are needed to cover operating expenses. This use of outlier payments is contrary to the intent of an outlier policy. Establishing an outlier policy allows us to ensure beneficiary access to services by sharing in the loss

associated with services for specific patients that are extraordinarily expensive. Through a comparison of the median per diem costs, we have determined that CMHCs dramatically increased their charges between CY 2001 and CY 2002. During this period, the median per diem cost for CMHCs increased by 58 percent. We believe that in most cases, these increases in charges were not related to a corresponding increase in costs. Since the CMHC cost-to-charge ratios used to calculate outlier payments remained constant during this period, we believe that the 58 percent increase in computed cost is attributable to artificial increases in charges designed to enhance outlier payments. Approximately two-thirds of outlier payments made to PHP providers were paid to 20 of the 125 CMHCs. The charges reported by these providers, on average, were over 10 times more than hospital per diem charges.

Given the difference in PHP charges between hospitals and CMHCs, we no longer believe it is appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Therefore, we are proposing to designate 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. CMHCs are projected to receive 0.36 percent of total OPPS payments in CY 2004, excluding outlier payments. Therefore, we are proposing to designate 0.36 percent of the estimated 2.0 percent outlier target amount for CMHCs and establish a threshold to achieve that level of outlier payments. Based on our simulations of CMHC payments in 2004, we are proposing to set the threshold for CY 2004 at 11.75 times the PHP APC payment amount. We believe that this approach would neutralize the impact of inflated CMHC charges on outlier payments. We are proposing to apply the same outlier payment percentage that applies to hospitals. Therefore, for CY 2004, we are proposing to pay 50 percent of CMHC per diem costs over the threshold. To the extent charges remain relatively constant, CMHCs would qualify for outlier payments in CY 2004 only for truly high cost patients.

As noted previously, we expect to receive updated cost-to-charge ratios from the FIs this summer. Many of the cost-to-charge ratios are expected to be considerably lower than those currently used to determine a provider's cost for the purpose of outlier and transitional pass-through or corridor payments. For example, we are aware of a number of situations where the updated cost-to-charge ratios have declined by more than 50 percent.

We specifically request public comments on this proposed outlier policy. We intend to monitor the extent to which the current pattern of escalating charges continues. CMS and the Office of the Inspector General will be further examining the excessive outlier payments to CMHCs.

XII. Summary of and Responses to MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) in its March 2002 Report to the Congress: ''Medicare Payment Policy,'' makes a number of recommendations relating to the OPPS. This section provides responses to those recommendations.

Recommendation: The Congress should increase payment rates for the OPPS by the rate of increase in the hospital market basket, less 0.9 percent, for CY 2004.

Response: Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor annually. Under section 1833(t)(3)(C)(iv) of the Act, the update must be equal to the hospital market basket percentage increase applicable under the hospital inpatient PPS. For years 2000 and 2002 only, the statute required the update to be determined by reducing the increase by one percentage point, but current law specifies such a reduction only for those 2 years. For 2004, we propose to increase the conversion factor by the rate of increase in the hospital market basket.

Recommendation: The Secretary should introduce clinical criteria for eligibility of drugs and biologicals to receive pass-through payments under the outpatient PPS.

Response: In accordance with section 402 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA), pass-through payments for medical devices is made on the basis of categories of devices. On November 2, 2001, we published in the **Federal Register** (66 FR 55850) a rule that specified the criteria for establishment of a new category of devices for purposes of pass-through payments. Among these is the requirement that the devices to be included in a possible category must demonstrate a substantial improvement in medical benefits for Medicare beneficiaries compared to benefits obtained by devices in previously established categories or other available treatments. We elaborated further about this criterion in the final rule updating the OPPS for CY 2003, published in the **Federal Register** on November 1, 2002. As we stated at that time, ''We established this criterion because it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, the need for additional payments for devices that offer little or no clinical improvement over a previously existing device is less apparent.'' (67 FR 66782)

At present, pass-through payment for drugs and biologicals is not made on the basis of categories, and no comparable criterion applies to them. Whether we should apply such a requirement to drugs and biologicals is an important question. On the one hand, as noted above, limiting extra payment to those items that have the potential to make a significant difference in treatment of Medicare beneficiaries appears useful. On the other hand, developing an appropriate mechanism for identifying which drugs or biologicals might qualify is difficult. Because the clinical characteristics of particular cases that are relevant for drug use may vary substantially, we believe that this challenge is more difficult than in the case of devices. Consequently, we have not developed a proposal in this area, and we are not prepared to advance one at this time.

XIII. Summary of Proposed Changes for 2004

A. Changes Required By Statute

We are proposing the following changes to implement statutory requirements:

- Add APCs, delete APCs, and modify the composition of some existing APCs.
- Recalibrate the relative payment weights of the APCs.
- Update the conversion factor and the wage index.
- Revise the APC payment amounts to reflect the APC reclassifications, the recalibration of payment weights, and the other required updates and adjustments.
- Cease transitional pass-through payments for drugs and biologicals and devices that will have been paid under the transitional pass-through methodology for at least 2 years by January 1, 2004.
- Cease transitional outpatient payments (TOPS payments) for all hospitals paid under OPPS except for cancer hospitals and children's hospitals.

B. Additional Changes

We are proposing the following additional changes to the OPPS:

- Adjust payment to moderate the effects of decreased median costs for non-pass-through drugs, biologicals, and radiopharmaceuticals.
- Implement a new method for paying for drug administration.
- Create new evaluation and management service codes for outpatient clinic and emergency department encounters.
- Change status indicators for HCPCS codes.
- List midyear and proposed HCPCS codes that are paid under OPPS.
- Allocate a portion of the outlier percentage target amount to CMHCs and create a separate threshold for outlier payments for partial hospitalization services.
- Create methodology and payment rates for separately payable drugs and radiopharmaceuticals for 2004.
- Make several changes in our current payment policy with regard to payment for Q0081, Q0083, Q0084, and Q0085 to facilitate accurate payments for drugs and drug administration.
- Change the status indicator and payment amount for P9010 by assigning it to APC 0957 (Platelet concentrate) with a payment rate of $37.30.

XIV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the 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.

The OPPS provisions set forth in this proposed rule do not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

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 respond to those comments in the preamble to that rule.

XVI. Regulatory Impact Analysis

A. 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 16, 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 2004 compared to CY 2003 to be approximately $0.457 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 Web site 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 define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area (MSA) and has fewer than 100 beds (or New England County Metropolitan Area (NECMA)). 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,