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42 CFR Parts 405 and 419

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2003 Payment Rates; and Changes to Payment Suspension for Unfiled Cost Reports; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405 and 419

[CMS–1206–FC and CMS–1179–F]

RIN 0938–AL19 and 0938–AK59

Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2003 Payment Rates; and Changes to Payment Suspension for Unfiled Cost Reports

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In addition, it describes changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. These changes are applicable to services furnished on or after January 1, 2003. This rule also allows the Secretary to suspend Medicare payments ''in whole or in part'' if a provider fails to file a timely and acceptable cost report.

In addition, this rule responds to public comments received on the November 2, 2001 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 payment under the Medicare's hospital outpatient prospective payment system. Finally, this rule responds to public comments received on the August 9, 2002 proposed rule for revisions to the hospital outpatient prospective payment system and payment rates (67 FR 52092). CMS finds good cause to waive proposed rulemaking for the assignment of new codes to Ambulatory Payment Classifications and for the payment of influenza and pneumococcal vaccines under reasonable cost; justification for the waiver will follow in a subsequent **Federal Register** notice.

DATES: *Effective date:* This final rule is effective January 1, 2003.

Comment date: We will consider comments on the ambulatory payment classification assignments of Healthcare Common Procedure Coding System codes identified in Addendum B with condition code NI, and on § 419.23(d)(3), if we receive them at the appropriate address, as provided below, no later than 5 pm on December 31, 2002.

FOR FURTHER INFORMATION CONTACT: Anita Heygster, (410) 786–0378—outpatient prospective payment issues; Lana Price, (410) 786–4533—partial hospitalization and end-stage renal disease issues; Gerald Walters, (410) 786–2070—payment suspension issues.

SUPPLEMENTARY INFORMATION:

Availability of Copies and Electronic Access

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Outline of Contents

I. Background

A. Authority for the Outpatient Prospective Payment System (OPPS)

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 August 24, 2001, we published a proposed rule (66 FR 44672) that would revise the OPPS to implement applicable statutory requirements, including relevant provisions of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2002 (BIPA) and changes arising from our continuing experience with this system. It also described proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the PPS. The changes applied to services furnished on or after January 1, 2002.

• On November 2, 2001, we published a final rule (66 FR 55857) that announced the Medicare OPPS conversion factor for calendar year 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. It 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 August 9, 2002, we published a proposed rule (67 FR 52092) that would revise the OPPS to implement applicable statutory requirements and changes arising from our continuing experience with this system. The changes would be applicable to services furnished on or afterJanuary 1, 2003. This rule also proposed to allow the Secretary to suspend Medicare payments ''in whole or in part'' if a provider fails to file a timely and acceptable cost report.

C. Authority for Payment Suspensions for Unfiled Cost Reports

Authority for the provision regarding payment suspensions for unfiled cost reports is contained within the authority for subpart C of 42 CFR part 405, that is, sections 1102, 1815, 1833, 1842, 1866, 1870, 1871, 1879, and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395cc, 1395gg, 1395hh, 1395pp, and 1395ccc) and 31 U.S.C. 3711.

D. Summary of Changes in the August 9, 2002 Proposed Rule

1. Changes Relating to the OPPS

On August 9, 2002, we published a proposed rule (67 FR 52092) that set forth proposed changes to the Medicare hospital OPPS and CY 2003 payment rates including changes used to determine these payment rates. The following is a summary of the major changes that we proposed and the issues we addressed in the August 9, 2002 proposed rule.

a. *Changes Required By Statute*

We proposed 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 (including blood and blood products) and devices (including brachytherapy), that will, on January 1, 2003, have been paid under transitional pass-through methodology for at least 2 years.

b. *Additional Changes to OPPS*

We proposed the following additional changes to the OPPS and Payment Suspension Provisions:

• Creation of new evaluation and management service codes for outpatient clinic and emergency department encounters for implementation no earlier than January 1, 2004.

• Changes to the list of services that we do not pay in outpatient departments because we define them as inpatient only procedures.

• Changes to our policy of nonpayment for procedures on the inpatient only list in special cases involving death or transfer before inpatient admission.

• Changes to our policy governing observation in cases of direct admission to observation.

• Changes to status indicators for Healthcare Common Procedure Coding System (HCPCS) codes.

• Changes to our policies governing dialysis for end-stage renal disease (ESRD) patients and regarding partial hospitalization.

C. Changes to the Regulations Text

A. We proposed to make the following changes to our regulations:

Amend § 419.66(c)(1) to specify that we must establish a new category for a medical device if it is not described by any category previously in effect as well as an existing category.

2. Changes Relating to Payment Suspension for Unfiled Cost Reports

We proposed to revise § 405.371(c) to specify that we may suspend Medicare payments ''in whole or in part'' if a provider has failed to timely file an acceptable cost report. This provision is consistent with the existing provisions in § 405.371(a) governing the suspension of Medicare payments ''in whole or in part'' under certain conditions. We believe the Medicare program would benefit because immediate complete payment suspension can be disruptive to providers and may negatively affect the care of Medicare patients.

E. Summary of the November 2, 2001 Interim Final Rule with Comment Period

On November 2, 2001, we published an interim final rule with comment period in the **Federal Register** (66 FR 55850) that set forth the criteria for establishing new categories of medical devices eligible for transitional pass-through payments under Medicare's hospital OPPS as required by section 1833(t)(6)(B)(ii) of the Act, as amended by BIPA.

In the April 7, 2000 final rule with comment period (65 FR 18480), we defined new or innovative devices using eight criteria, three of which were revised in our August 3, 2000 interim final rule with comment period (65 FR 47673–74). These criteria remained applicable when defining a new category for devices, (that is, devices to be included in a category must meet all previously established applicable criteria for a device eligible for transitional pass-through payments) but we revised the definition of an eligible device to conform the requirements of amended section 1833(t)(6)(B)(ii) of the Act.

We also clarified our criterion that states that a device must be approved or cleared by the Food and Drug Administration (FDA).

In establishing the criteria for establishing additional categories, the Act mandates that new categories be established for devices that were not being paid for as an outpatient hospital service as of December 31, 1996 and for which no categories in effect (or previously in effect) are appropriate, in such a way that no device is described by more than one category and the average cost of devices to be included in the category is not insignificant in relation to the APC payment amount for the associated service. Based on these requirements, we used the following criteria to establish a category of devices:

• *Substantial clinical improvement.* The category describes devices that demonstrate a substantial improvement in medical benefits for Medicare beneficiaries compared to the benefits obtained by devices in previously established categories or other available treatments, as described in regulations at new § 419.66(c)(1).

• *Cost.* We determine that the estimated cost to hospitals of the devices in a new category (including any candidate devices and the other devices that we believe will be included in the category) is ''not insignificant'' relative to the payment rate for the applicable procedures.

We received five timely items of correspondence on the November 2, 2001 interim final rule with comment period. Summaries of the public comments and our responses to those comments are set forth below under the appropriate section heading of this final rule with comment period.

F. Public Comments and Responses to the August 9, 2002 Proposed Rule

We received approximately 1,000 timely items of correspondence containing multiple comments on the August 9, 2002 proposed rule. Of that total, we received eight comments relating to the payment suspension provision described in section I.D.2. Summaries of the public comments received on other provisions and our responses to those comments are provided below in section I.F.2 of this preamble.

1. OPPS

We received comments from various sources including but not limited to health care facilities, physicians, drug and device manufacturers, and beneficiaries. Hospital associations and the Medicare Payment Advisory Commission (MedPAC) generally supported our proposed approach to revising the relative weights and incorporating the drugs and devices into payment for APCs. Pharmaceutial and medical device manufacturers and some individual hospitals that furnish particular devices or drugs were concerned with the proposed reductions in payment for medical devices and drugs. We received many thoughtful comments from a wide range of commenters with regard to methodological issues in OPPS. In addition, several comments provided data to support their assertions. The following are the major OPPS related issues addressed by the commenters:

• Expiration of pass-through payment for most devices and drugs/biologicals.

• Extent of reduction in payments for devices compared to payments in 2002.

• Potential impact on access to care of proposed payments.

• The proposal to package drugs with a per line cost less than $150 and to pay separately for others.

• Assignment and reassignment of codes to APCs (including assignments to procedural APCs from new tech APCs).

• Quality, quantity and content of claims data used to set payment weights.

• Continuation of a list of procedures that are not paid under OPPS because we believe that they should be performed as inpatient services.

• Policy on payment for outpatient observation care.

• Creation of evaluation and management codes for OPPS use.

Summaries of the public comments received and our responses to those comments are set forth below under the appropriate headings of this final rule with comment period.

2. Payment Suspension for Unfiled Cost Reports

Comments and Responses

Comment: All of the commenters stated that the rule provides for increased flexibility and a reduction in the financial impact of payment suspensions on providers. They indicated the increased flexibility would allow providers to receive partial payments from Medicare, which would lessen the financial impact of payment suspensions.

Response: We appreciate the hospital associations supporting this change.

Comment: One commenter suggested that payment suspension be limited to those payments directly determined by the cost report.

Response: We believe that immediate suspension of all payments when a cost report is not filed timely may not always be the appropriate response. However, if we require a provider to file a cost report, it is important for the cost report to be filed in a timely manner regardless of the amount of payment that is determined based on the cost report. We need flexibility in determining the amount of a provider's payments to suspend if its cost report is not filed timely. This could include the potential suspension of payments that are not determined by the cost report. Thus, we will retain § 405.371 of the regulation as set forth in the proposed rule.

II. 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 and related payment adjustment factors to take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information. Section 1833(t)(9)(A) of the Act requires the Secretary, beginning in 2001, to consult with an outside panel of experts when annually reviewing and updating 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 item or service in the group is more than 2 times greater than the lowest median cost 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 the proposed rule and for this final rule with comment period, we analyzed the APC groups within this statutory framework.

A. Recommendations of the Advisory Panel on APC Groups

1. Establishment of the Advisory Panel

Section 1833(t)(9)(A) of the Act, requires that we consult with an outside panel of experts when annually reviewing and updating the APC groups and the relative weights. The Act specifies that the panel will act in an advisory capacity. The expert panel, which is to be composed of representatives of providers, is to review and advise 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). 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). 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 themselves or a colleague. After carefully reviewing the applications, we chose 15 highly qualified individuals to serve on the Panel. The first APC Panel meeting was held on February 27, February 28, and March 1, 2001, to discuss the 2001 APCs in anticipation of the 2002 OPPS.

We published a notice in the **Federal Register** on December 14, 2001, to announce the location and time of the second Panel meeting, a list of agenda items, and that the meeting was open to the public. We also provided additional information through a press release and on our Web site. We convened the second meeting of the Panel on January 22 through January 24, 2002.

2. General Issues Considered by the Advisory Panel

In the proposed rule, we summarized the Panel's discussion of a recommendation by the Panel's Research Subcommittee concerning the format of written submissions and oral presentations to the Panel and of several general OPPS payment issues.

Content for Future Presentations to the Panel

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 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 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 the Subcommittee s recommendation. Presentations for the 2003 meeting must contain, at a minimum, this information.

Inpatient Only List

At its February 2001 meeting, the Panel discussed the existence of the inpatient list. The Panel favored its elimination. At the January 2002 meeting, Panel members noted that hospitals receive no payment for a service performed in an outpatient department that appears on the inpatient list, even though the physician performing that service will receive payment for his or her services. The Panel believes the physician should determine what procedure to perform and that both the hospital and the physician should receive payment for the procedure. We continue to disagree with the position taken by the Panel regarding the inpatient list for reasons that we discuss in detail in the April 7, 2000 final rule (65 FR 18456).

Prior to the 2002 Panel meeting, we received requests from hospital and surgical associations and societies to remove certain procedures from the inpatient list. We reviewed those requests and presented to the Panel the requests for which we were unable to make a determination based on the information submitted with the request.

The Panel considered removing the following procedures from the inpatient list:

CPT	Description
21390	Treat eye socket fracture
27216	Treat pelvic ring fracture
27235	Treat thigh fracture

CPT	Description
32201	Drain, precut, lung lesion
33967	Insert a precut device
47490	Incision of gallbladder
62351	Implant spinal canal cath
64820	Remove sympathetic nerves
92986	Revision of aortic valve
92987	Revision of mitral valve
92990	Revision of pulmonary valve
92997	Pul art balloon repr, precut
92998	Pul art balloon repr, precut

As the Panel recommended, we solicited comments and additional information from hospitals and medical specialty societies that have an interest in these procedures. At their 2003 meeting, the Panel also recommended that we present to them any such comments that we receive to assist in their evaluation of whether to recommend removing the codes from the inpatient list.

The Panel did recommend that we remove from the inpatient list CPT code 47001, Biopsy of liver, needle; when done for indicated purpose at time of other major procedure. We agreed with the Panel's recommendation and we proposed to remove 47001 from the inpatient list. We further proposed to assign it status indicator ''N'' so that costs associated withCPT code 47001 would be packaged into the APC payment for the primary procedure performed during the same operative session.

In section II.B.5 of the proposed rule, we discussed additional procedures, which were not considered by the Panel, that we proposed to remove from the inpatient list. We discussed in detail our reasons for proposing these additional changes, and we proposed two new criteria that we would adopt in the future when evaluating whether to make a procedure on the inpatient list payable under the OPPS. Table 6 in section II.B.5 of the proposed rule lists all the procedures we proposed to remove from the inpatient list, including those discussed by the Panel. We considered the removal of CPT code 33967, Insertion of intra-aortic balloon assist device, percutaneous from the inpatient list, but did not include it in Table 6. The Panel considered this code for removal from the inpatient list and had concerns about whether performing this procedure in an outpatient setting is appropriate. Further, we were not able to confirm that this procedure is being performed on Medicare beneficiaries in an outpatient setting. We solicited comments, including clinical data and specific case reports, which would support payment for CPT 33967 under the OPPS.

Our discussion of the comments we received on this issue, our response and the statement of final action regarding what services to remove from the inpatient list is contained in section II.B.5.

Multiple Bills

During its February 2001 meeting, the Panel received oral testimony identifying CMS exclusive use of single procedure claims to set relative weights for APCs as a potential problem in setting appropriate payment rates for APCs. Therefore, the panel asked its Research Subcommittee to work with CMS staff, using the Endoscopic Retrograde Cholangiopancreatography (ERCP) code family as a case study, to explore the use of multiple procedure claims data for setting relative weights.

The Subcommittee made the following recommendations to the Panel, which the Panel approved:

- We should continue to explore the use of multiple procedure claims data for setting payment rates but should continue to use only single procedure claims data to determine relative payment weights for CY 2003.
- We should work with the APC Panel to explore the use of multiple claims data drawn from OPPS claims for services such as radiation oncology in time for the next APC Panel meeting.
- We should educate hospitals on appropriate coding and billing practices to ensure that claims with multiple procedures are properly coded and that costs are properly allocated to each procedure.

One presenter to the panel suggested a method to increase the number of claims that could be considered as single claims. Currently, we consider any claim submitted with two or more primary codes (that is, a code assigned to an APC for separate payment) to be a multiple procedure claim. When these claims contain line items for revenue centers without an accompanying Healthcare Common Procedure Coding System (HCPCS) code there is no way to determine the appropriate primary code with which to package the revenue center. The presenter suggested that we consider all claims where every line contains a separately payable HCPCS code as a single procedure claim, reasoning that on such claims we do not have to determine how and where to ''package'' line items not identified by a separately payable HCPCS code. Where every line item contains a separately payable HCPCS code, every cost can easily be allocated to a separately payable HCPCS code on the line item and all costs for each HCPCS code can then be accurately and completely determined.

We agreed with that suggestion. In section II.B.4 of the proposed rule, we described how we determined the number of single claims used to set the APC relative weights proposed for 2003 using this methodology. We requested comments on our methodology.

Discussion of the comments we received on this issue, our responses, and the statement of final action are contained in section III.A.

Packaging

We sought the Panel's guidance on whether we should package the costs of HCPCS codes for radiologic guidance and radiologic supervision and interpretation services whose descriptors require that they only be performed in conjunction with a surgical procedure.

In the proposed rule, we discussed why we package the costs of certain procedures. We specified for example, that ''add-on'' procedures and radiologic guidance procedures should never be billed on a claim without the code for an associated procedure. A facility should not submit a claim for ultrasound guidance for a biopsy unless the claim also includes the biopsy procedure, because the guidance is necessary only when a biopsy is performed. A claim for a packaged guidance procedure (or a supervision and interpretation procedure whose descriptor requires it be performed in association with a surgical procedure)

would be returned to the provider for correction and resubmission.

Also, we explained that we use packaging because billing conventions allow hospitals to report costs for certain services using only revenue center codes (that is, hospitals are not required to specify HCPCS codes for certain services). Packaging allows these costs to be captured in the data used to calculate median costs for services with an APC.

After hearing the requests of several presenters, (details discussed at 66 FR 52098 of the proposed rule) the Panel concluded that, even though we could be setting relative weights based on error claims, we should not package additional radiologic guidance and supervision and interpretation procedures and should continue to explore methodologies that would allow these procedures to be recognized for separate payment. The Panel also recommended that radiology guidance codes that were in APC 268 for CY 2001 but that were designated with status indicator ''N'' as packaged services in 2002, be restored as separately payable services for CY 2003. The Panel requested that this topic be placed on the agenda for the next Panel meeting.

Our discussion of the comments we received on this issue, our responses and a statement of final action is contained in section III.B.

Add-On Codes

As discussed in the proposed rule (66 FR 52098), we presented for the Panel's consideration several options for payment of add-on codes, including assignment of status indicator ''N'' to package them into the payment for the base procedure. After thorough review, the Panel concluded that we should continue to pay for add-on codes separately, setting relative weights with the use of single procedure claims in spite of the fact that these were error claims. The Panel asked us to continue exploring ways to most appropriately pay for these services. They requested that this item also be placed on the agenda for the next Panel meeting.

We proposed to accept the recommendations of the APC Panel both for packaging radiology guidance and supervision and interpretation codes and for payment of add-on codes. We proposed to pay separately in 2003 for radiology guidance codes that were paid in APC 268 in CY 2001 but that were packaged in 2002.

3. Recommendations of the Advisory Panel and Our Responses

In the proposed rule, we summarized the issues considered by the Panel, the Panel's APC recommendations and our subsequent action with regard to the Panel's recommendations. The most recent data available for the Panel to review in considering specific APC groupings were the 1999–2000 pre-OPPS claims data that were the basis of the CY 2002 relative payment weights. In the proposed rule, we provided a detailed summary of the Panel discussion and recommendations (67 FR 52098–52102). See the proposed rule for more details regarding these discussions. The APC titles are shown in this discussion of the APC Panel recommendations as they existed when the APC Panel met in January 2002. In a few cases the APC titles were changed for the proposed 2003 OPPS and therefore some APCs do not have the same title in Addendum A as they have in this section.

As discussed below, the Panel sometimes declined to recommend a change in an APC even though the APC violated the 2 times rule. In section II.B.1 of this preamble, we discuss our proposals regarding the 2 times rule based on the CY 2001 data we are using to recalibrate the 2003 APC relative weights. Section II.B.1 also details the criteria we use in deciding to make an exception to the 2 times rule. We asked the Panel to review many of the exceptions we implemented in 2001 and 2002. We refer to the exceptions as ''violations of the 2 times'' rule in the following discussion.

APC 215: Level I Nerve and Muscle Tests
APC 216: Level III Nerve and Muscle Tests
APC 218: Level II Nerve and Muscle Tests

We presented this agenda item because APC 215 appeared to violate the 2 times rule. In order to remedy this violation, we asked the Panel to consider the following changes:

- Move CPT codes 95858, 95921, and 95922 from APC 215 to APC 218.
- Move CPT code 95930 from APC 216 to APC 218.
- Move CPT code 92275 from APC 216 to APC 231.
- Move CPT code 95920 from APC 218 to APC 216.

The Panel recommended that the changes we asked them to consider be made, that is, to move CPT codes 95921 and 95922 to APC 218. However, if the calendar year 2001 data support a move of 95921 to APC 216, the Panel recommended that we consider that move.

APC 600: Low Level Clinic Visits
APC 601: Mid Level Clinic Visits
APC 602: High Level Clinic Visits
APC 610: Low Level Emergency Visits
APC 611: Mid Level Emergency Visits
APC 612: High Level Emergency Visits

We discussed the Panel's recommendations related to facility coding for clinic and emergency department visits are discussed below, in (section X.A of this rule).

APC 296: Level I Therapeutic Radiologic Procedures
APC 297: Level II Therapeutic Radiologic Procedures
APC 263: Level I Miscellaneous Radiology Procedures
APC 264: Level II Miscellaneous Radiology Procedures

APCs 296, 263, and 264 appear to violate the 2 times rule. We asked the Panel to consider three options for reconfiguring these APCs so that they would conform with the 2 times rule.

Option 1: Create a new APC, Level III Therapeutic Radiology Procedures, by moving CPT code 75984 from APC 296 and 74475 from APC 297. Also, move CPT codes 76101, 70390, and 71060 from APC 263 to APC 264 and move CPT code 75980 from APC 297 to APC 296.

Option 2: Move CPT codes 76101, 703690, and 71060 from APC 263 to APC 264 and move CPT code 75984 from APC 296 to APC 264. Move CPT code 75980 from APC 297 to APC 296.

Option 3: Create a new APC, Level III Miscellaneous Radiology

Procedures, by moving CPT codes 76080, 7036736, 76101, 70390, 74190, and 71060 from APC 263. Move CPT code 74327 from APC 296 to APC 263 and move CPT code 75980 from APC 297 to APC 296. APC 264 remains unchanged.

The Panel noted that none of the options that we presented resolve all of the 2 times violations. However, the Panel agreed that Option 2 would create more clinically coherent APCs without creating a new APC based on anticipated device costs that would be billed in 2002. In addition, the Panel invited the American College of Radiology and other interested parties to proposed further changes for the Panel's consideration next year.

We proposed to accept the Panel's recommendations that option 2 be implemented.

APC 230: Level I Eye Tests and Treatments
APC 231: Level III Eye Tests and Treatments
APC 232: Level I Anterior Segment Eye Procedures
APC 233: Level II Anterior Segment Eye Procedures
APC 234: Level III Anterior Segment Eye Procedures

APC 235: Level I Posterior Segment Eye Procedures
APC 236: Level II Posterior Segment Eye Procedures
APC 237: Level III Posterior Segment Eye Procedures
APC 238: Level I Repair and Plastic Eye Procedures
APC 239: Level II Repair and Plastic Eye Procedures
APC 240: Level III Repair and Plastic Eye Procedures
APC 241: Level IV Repair and Plastic Eye Procedures
APC 242: Level V Repair and Plastic Eye Procedures
APC 247: Laser Eye Procedures Except Retinal
APC 248: Laser Retinal Procedures
APC 698: Level II Eye Tests and Treatments
APC 699: Level IV Eye Tests and Treatments

We asked the Panel to review these APCs to address clinical inconsistencies and violations of the 2 times rule. We suggested creating a new level for posterior segment eye procedures and other changes in order to make the groups more clinically coherent, as follows:

- Move CPT codes 65260 and 67218 from APC 237 to 236.
- Create a new APC (Level IV Posterior Segment Eye Procedures) by moving CPT codes 67107, 67112, 67040, and 67108 from APC 237.
- Move CPT codes 67145, 67105, and 67210 from APC 247 to APC 248.
- Move CPT code 66999 from APC 247 to APC 232.
- Move CPT code 67299 from APC 248 to APC 235.
- Move CPT codes 65855, 66761, and 66821 from APC 248 to APC 247.
- Move CPT code 67820 from APC 698 to APC 230.
- Move CPT code 67208 from APC 231 to APC 235.
- Move CPT codes 92226, 92284, 65205, 92140 from APC 231 to APC 698.
- Move CPT code 92235 from APC 231 to APC 699.
- Move CPT code 68100 from APC 233 to APC 232.
- Move CPT code 65180 from APC 233 to APC 234.
- Create a new APC (Level IV Anterior Segment Eye Procedures) by moving CPT codes 66172, 66185, 66180, 66225 from APC 234.
- Move CPT code 92275 from APC 216 to APC 231.

No presenters commented on these APCs, and, after brief discussion, the Panel recommended concurrence with our suggested changes. We proposed to accept the Panel's recommendations. We noted in the proposed rule that when we were able to use 2001 claims data to re-evaluate the changes recommended by the Panel for these APCs, we found violations of the 2 times rule in the reconfigured APCs. Nonetheless, we proposed to accept the Panel's recommendations because they result in more clinically coherent APCs. We solicited comments on further changes that would address the violations of the 2 times rule.

APC 110: Transfusion
APC 111: Blood Product Exchange
APC 112: Apheresis, Photopheresis, and Plasmapheresis

We presented these APCs to the Panel in 2001 because of their low payment rates and concern that our cost data were inaccurate. These APCs were on the 2002 agenda in order to obtain further comment on our cost data. We suggested no changes in the structure of these APCs.

The Panel recommended that plasma derivatives be placed in their own APCs and classified in the same manner as whole blood products. In addition, the Panel observed that hospitals incur additional costs with each unit of blood product transfused and, therefore, recommended that APC 110 be revised to allow for the costs of additional units of blood product and clinical services.

In section IV.D of this rule, we discussed our payment proposals for drugs and biologicals for which pass-through payments are scheduled to expire in 2003. Those proposals would affect payment for blood and blood products. We proposed not to accept the Panel's recommendation to change current OPPS payment policy for transfusions.

Panel Recommendations to Defer Changes Pending Availability of 2001 Claims Data

Regarding the remaining APC groups that are addressed below, the Panel recommended that we make no changes until data from claims billed in 2001 under the OPPS become available for analysis. The Panel further requested that we place the APC groups in this section on the agenda for consideration at its meeting in 2003. The changes that we proposed for the APCs in this section are based upon our review of the 2001 claims data, which did not become available until March 2002.

APC 203: Level V Nerve Injections
APC 204: Level VI Nerve Injections
APC 206: Level III Nerve Injections
APC 207: Level IV Nerve Injections

Several presenters to the Panel suggested changes in the configuration of these APCs 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 the APCs. Several of these APCs include procedures associated with drugs or with device categories for which pass-through payments are scheduled to expire in 2003. The Panel recommended that we not change the structure of these APCs at this time. Because the structure of these APCs was substantially changed for 2002, and 2002 cost data was not yet available, the Panel felt it would be appropriate to review 2002 cost data prior to making further structural changes to these APCs. We proposed to accept the Panel's recommendation.

We will place these APCs on the Panel's agenda when 2002 cost data becomes available.

APC 43: Closed Treatment Fracture Finger/Toe/Trunk
APC 44: Closed Treatment Fracture/Dislocation, Except Finger/Toe/Trunk

On the basis of 1999–2000 claims data, these APCs violate the 2 times rule. The Panel reviewed these APCs and recommended no changes.

Our subsequent review of 2001 OPPS cost data shows continuing violations of the 2 times rule and that costs within these APCs are virtually identical. Therefore, we proposed to combine APCs 43 and 44 into APC 43. The procedures in the consolidated APC are clinically homogeneous.

APC 58: Level I Strapping and Cast Application
APC 59: Level II Strapping and Cast Application

The Panel reviewed these APCs and recommended that no changes be made pending analysis of 2001 claims data. The Panel did recommend that billing instructions be developed on the appropriate use of the codes in these APCs. We agreed with the Panel's recommendation regarding the need for billing instructions, and we expect to develop such instructions for hospitals to use in 2003.

Our subsequent review of 2001 claims data reveals that, in some cases, costs for short casts and splints are greater than costs for long casts and splints. Moreover, the proposed payments for these two APCs, based on 2001 OPPS data, would not differ significantly from each other. Therefore, we proposed to combine the codes in APC 58 and APC 59 into a single APC, APC 58. Combining these APCs does not compromise clinical homogeneity. The relative weight of the proposed single APC is virtually identical to the relative weight of each of the two current APCs. We proposed to continue to work with hospitals to develop appropriate coding

for these services and will review the appropriate APC structure for these services next year.

APC 279: Level I Angiography and Venography Except Extremity
APC 280: Level II Angiography and Venography Except Extremity

Without the benefit of 2001 OPPS claims data, it was difficult for the Panel to determine whether the apparent violation of the 2 times rule in APCs 279 and 280 was attributable to underreporting of procedures or inaccurate coding. Therefore, the Panel recommended no changes pending the availability of the more recent claims data. After subsequently reviewing the 2001 claims data, we proposed to move CPT codes 75978, Transluminal balloon angioplasty, venous, radiological supervision and interpretation, and 75774, Angiography, selective, each additional vessel studied after basic examination, radiological supervision and interpretation, to new APC 0668. This would resolve violations of the 2 times rule and result in clinically coherent APCs.

APC 115: Cannula/Access Device Procedures

We proposed to move CPT code 36860, External Cannula Declotting; without balloon catheter, to APC 103, Miscellaneous Vascular Procedures. We believe this makes both APC 115 and APC 103 more clinically homogeneous and it resolves a violation of the 2 times rule in APC 115 that was caused by the presence of CPT code 36860.

APC 93: Vascular Repair/Fistula Construction
APC 140: Esophageal Dilation without Endoscopy
APC 141: Upper GI Procedures
APC 142: Small Intestine Endoscopy
APC 143: Lower GI Endoscopy
APC 144: Diagnostic Anoscopy
APC 145: Therapeutic Anoscopy
APC 146: Level I Sigmoidoscopy
APC 147: Level II Sigmoidoscopy
APC 148: Level I Anal/Rectal Procedure
APC 149: Level II Anal/Rectal Procedure

Our subsequent review of 2001 claims data suggests that the cost data for APCs 144 and 145 are aberrant. The cost data for these APCs yield relative weights and payments that are significantly higher than the relative weights for APCs 146 and 147, which consist of similar procedures performed through a sigmoidoscope rather than an anoscope. As currently arranged, the APC configuration for these services could provide a financial incentive for hospitals to perform unnecessary anoscopic procedures, either alone or with a sigmoidoscopy. To rectify this problem, we proposed to move the procedures in APCs 144 and 145 to APC 147 with the exception of CPT code 46600, Anoscopy; diagnostic, which we proposed to assign to APC 340, Minor Ancillary procedures. We believe these changes would result in clinically coherent APCs with appropriate relative weights and payment rates.

APC 363: Otorhinolaryngologic Function Tests

Based on 2001 claims data, we proposed to move CPT codes 92543, 92588, 92520, 92546, 92516, 92548, and 92584 to new APC 0660 (Level III Otorhinolaryngolgic Function Tests). This change would resolve a 2 times rule violation and create clinically coherent APCs.

APC 96: Non-Invasive Vascular Studies
APC 265: Level I Diagnostic Ultrasound Except Vascular
APC 266: Level II Diagnostic Ultrasound Except Vascular
APC 267: Vascular Ultrasound
APC 269: Level I Echocardiogram Except Transesophageal
APC 270: Transesophageal Echocardiogram

The APC Panel recommended making no changes in the configuration of these APCs. Based on 2001 claims data, we proposed to make several changes in order to resolve 2 times rule violations and to make these APCs more clinically coherent. Specifically, we proposed to move CPT code 43499 from APC 0140 to APC 141; CPT code 93721 from APC 0096 to APC 368; CPT code 93740 from APC 0096 to APC 367; CPT code 93888 from APC 0267 to APC 266; and CPT code 93931 from APC 0267 to APC 266. We also proposed to move CPT codes 78627, 76825, and 93320 from APC 0269 to new APC 0671 to achieve more clinical coherence. We also proposed to create new APC 0670 for intravascular ultrasound and intracardiac echocardiography consisting of CPT codes 37250, 37251, 92978, 92979, and 93662.

APC 291: Level I Diagnostic Nuclear Medicine Excluding Myocardial Scans
APC 292: Level II Diagnostic Nuclear Medicine Excluding Myocardial Scans

Subsequent to the APC Panel meeting, we received comments on these APCs from the Nuclear Medicine Task Force. After a thorough review of that proposal within the context of the 2001 claims data, we proposed to accept the recommendations of the Nuclear Medicine Task Force, which would result in a complete reconfiguration of APCs 290, 291, and 292. Although the reconfiguration would create violations of the 2 times rule, we agree with the Task Force that the reconfigured APCs are more clinically coherent. We note that APCs 290, 291, and 292 as currently configured would also violate the 2 times rule. Therefore, we solicited comments on the proposed reconfiguration of APCs 290, 291, and 292 and on alternative groupings that would achieve clinical coherence without violating the 2 times rule.

APC 274: Myleography
APC 179: Urinary Incontinence Procedures
APC 182: Insertion of Penile Prosthesis
APC 19: Level I Excision/Biopsy
APC 20: Level II Excision/Biopsy
APC 21: Level IV Excision/Biopsy
APC 22: Level V Excision/Biopsy
PC 694: Level III Excision/Biopsy

Based on 2001 claims data, we proposed to move several codes from APC 19 to APC 20 and several codes from ACP 20 to APC 21. Additionally, we proposed to move CPT codes 11770, 54105, and 60512 to APC 22. We also proposed to move CPT code 58999 to APC 191 and CPT code 37799 to APC 35. These changes would result in clinically coherent APCs that do not violate the 2 times rule.

APC 24: Level I Skin Repair
APC 25: Level II Skin Repair
APC 26: Level III Skin Repair
APC 27: Level IV Skin Repair
APC 686: Level V Skin Repair

Based on 2001 claims data, we proposed to move CPT code 43870 from APC 0025 to APC 141; and CPT codes with high costs from APC 26 to APC 27. We also proposed to move the codes remaining in APC 26 to APC 25. APC 26 would then be deleted. These changes would result in a more compact APC structure without compromising the clinical homogeneity of the reconfigured APCs and without violating the 2 times rule. See Table 1 for the final list of codes to be moved from APC 26 to APC 25 or APC 27.

TABLE 1.—HCPCS CODES TO BE MOVED FROM APC 26 INTO APC 25 OR APC 27

2002 APC 26	2003 APC 25	2003 APC 27
11960		11960
11970		11970
12037	12037	
12047	12047	
12057	12057	
13150	13150	
13160		13160
14000		14000
14001		14001

TABLE 1.—HCPCS CODES TO BE MOVED FROM APC 26 INTO APC 25 OR APC 27—Continued

2002 APC 26	2003 APC 25	2003 APC 27
14020		14020
14021		14021
14040		14040
14041		14041
14060		14060
14061		14061
14300		14300
14350		14350
15000	15000	
15001	15001	
15050	15050	
15101		15101
15120		15120
15121		15121
15200		15200
15201	15201	
15220		15220
15221	15221	
15240		15240
15241	15241	
15260		15260
15261	15261	
15351		15351
15400	15400	
15401	15401	
15570		15570
15572		15572
15574		15574
15576		15576
15600		15600
15610		15610
15620		15620
15630		15630
15650		15650
15775	15775	
15776	15776	
15819	15819	
15820		15820
15821		15821
15822		15822
15823		15823
15825		15825
15826		15826
15829		15829
15835	15835	
20101		20101
20102		20102
20910		20910
20912		20912
20920		20920
20922		20922
20926		20926
23921	23921	
25929		25929
33222		33222
33223		33223
44312		44312
44340		44340
15580—Code Deleted		
15625—Code Deleted		

APC 77: Level I Pulmonary Treatment
APC 78: Level II Pulmonary Treatment
APC 251: Level I ENT Procedures
APC 252: Level II ENT Procedures
APC 253: Level III ENT Procedures
APC 254: Level IV ENT Procedures
APC 256: Level V ENT Procedures

Based on 2001 claims data, we proposed to address violations of the 2 times rule by moving CPT codes 40812, 42330, and 21015 from APC 0252 to APC 253 and by moving CPT codes 41120 and 30520 to APC 254.

We are adopting the changes discussed in the proposed rule as final except as noted in our discussion of specific APC changes in section II.B, below.

B. Other Changes Affecting Ambulatory Payment Classification (APC) Assignments

1. Limit on Variation of Costs of Services Classified Within a 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 a 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 group in unusual cases such as low-volume items and services. No exception may be made, however, 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 APC changes discussed in relation to the APC panel recommendations in this section of this preamble and the use of 2001 claims data to calculate the median cost of procedures classified to APCs, we reviewed all 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).

We received several comments on this proposal. A summary of these comments and our responses are provided below.

Comment: One commenter recommended that we move CPT code 47556 (Biliary endoscopy with dilation of biliary stricture with stent) from APC 0152 to APC 0153 because its placement in APC 0152 violated the 2 times rule.

Response: We will not make any changes at this time, but we will present this issue to the APC Advisory Panel. We do not use low-volume procedures in determining whether an APC violates the 2 times rule because there is a high potential for miscoding of such procedures and because our cost data is less reliable. The cost data that we do have for CPT 47556 indicates that APC 0152 is appropriate.

Comment: Several commenters thanked us for creating a separate APC for Computed Tomographic Angiography (CTA) but requested that we not use claims data to develop a payment rate. These commenters asserted that our claims data was faulty because hospitals had not developed specific charges for CTA and were using charges for other Computed Tomography (CT) when billing for CTA. They recommended that we use either the relative ratio of charges from hospitals that billed CTA at a higher rate than CT and use that ratio to determine a payment rate for CTA, or use a proxy model that the commenter had developed.

Response: Our payment rates for CT and CTA are different and our claims data indicates that CTA costs more than CT. Using claims data only from hospitals that charge more for CTA than CT is inappropriate, and the proxy model has not been validated. Therefore, we will update our payment for CTA next year based on 2002 claims data.

Table 2 contains the final list of APCs that we exempt from the 2 times rule based on the criteria cited above. In cases in which compliance with the 2 times rule appeared to conflict with a recommendation of the APC Advisory Panel, we generally accepted the Panel recommendation. This was 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 2.—TABLE OF APCS EXEMPTED FROM 2 TIMES RULE

APC	Description
0012	Level I Debridement & Destruction
0019	Level I Excision/ Biopsy
0020	Level II Excision/ Biopsy
0025	Level II Skin Repair
0032	Insertion of Central Venous/Arterial Catheter
0043	Closed Treatment Fracture Finger/ Toe/Trunk
0046	Open/Percutaneous Treatment Fracture or Dislocation

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

APC	Description
0058	Level I Strapping and Cast Application
0074	Level IV Endoscopy Upper Airway
0080	Diagnostic Cardiac Catheterization
0081	Non-Coronary Angioplasty or Atherectomy
0093	Vascular Repair/Fistula Construction
0097	Cardiac and Ambulatory Blood Pressure Monitoring
0099	Electrocardiograms
0103	Miscellaneous Vascular Procedures
0105	Revision/Removal of Pacemakers, AICD, or Vascular
0121	Level I Tube changes and Repositioning
0140	Esophageal Dilation without Endoscopy
0147	Level II Sigmoidoscopy
0148	Level I Anal/Rectal Procedure
0155	Level II Anal/Rectal Procedure
0165	Level III Urinary and Anal Procedures
0170	Dialysis
0179	Urinary Incontinence Procedures
0191	Level I Female Reproductive Proc
0192	Level IV Female Reproductive Proc
0203	Level VI Nerve Injections
0204	Level I Nerve Injections
0207	Level III Nerve Injection
0218	Level II Nerve and Muscle Tests
0225	Implantation of Neurostimulator Electrodes
0230	Level I Eye Tests & Treatments
0231	Level III Eye Tests & Treatments
0233	Level II Anterior Segment Eye Procedures
0235	Level I Posterior Segment Eye Procedures
0238	Level I Repair and Plastic Eye Procedures
0239	Level II Repair and Plastic Eye Procedures
0252	Level II ENT Procedures
0260	Level I Plain Film Except Teeth
0274	Myelography
0286	Myocardial Scans
0290	Level I Diagnostic Nuclear Medicine Excluding Myocardial Scans
0291	Level II Diagnostic Nuclear Medicine Excluding Myocardial Scans
0294	Level I Therapeutic Nuclear Medicine
0297	Level II Therapeutic Radiologic Procedures
0303	Treatment Device Construction
0304	Level I Therapeutic Radiation Treatment Preparation
0330	Dental Procedures
0345	Level I Transfusion Laboratory Procedures
0354	Administration of Influenza/Pneumonia Vaccine
0356	Level II Immunizations
0367	Level I Pulmonary Test
0368	Level II Pulmonary Tests
0370	Allergy Tests
0373	Neuropsychological Testing
0600	Low Level Clinic Visits

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

APC	Description
0602	High Level Clinic Visits
0660	Level III Otorhinolaryngologic Function Tests
0692	Electronic Analysis of Neurostimulator Pulse Generators
0694	Mohs Surgery
0698	Level II Eye Tests & Treatments

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

In the November 30, 2001 final rule, we made final our proposal to change the period of time during which a service may be paid under a new technology APC (66 FR 59903), initially established in the April 7, 2000 final rule. That is, beginning in 2002, we will 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.

Effective in 2003, we will move several procedures from new technology APCs to clinical APCs. Those procedures and the clinical APCs to which we are assigning the procedures for payment in 2003 are identified in Table 3. Based upon our review of the 2001 outpatient prospective payment system (OPPS) claims data, we believe that we have sufficient information upon which to base assignment of these procedures to clinical APCs. In making this determination, we reviewed both single and multiple procedure claims. In the proposed rule at 67 FR 52103, we discuss the procedures that we followed to make this determination. In some cases we proposed classification of a new technology procedure in an APC with procedures that are similar both clinically and in terms of resource consumption. In other cases, we proposed to create a new APC for a new technology procedure because we do not believe any of the existing APCs contain procedures that are clinically similar and similar in terms of resource consumption. We solicited comments on our proposed reassignment of the new technology procedures listed in Table 3 of the proposed rule (67 FR 52103–52104).

We received several comments on this proposal which are summarized below.

Comment: Several commenters brought to our attention that, as a result of moving codes for proton beam radiation therapy out of APC 0710 and APC 0712 (new technology codes) and into APC 0664 (Proton beam radiation therapy), simple treatments would receive a higher payment while intermediate and complex treatments would receive a lower payment. Commenters requested that these codes remain in APCs 0710 and 0712 or be split into separate APCs.

Response: We thank the commenters for bringing this to our attention, and we agree that codes for simple proton beam radiation therapy (CPT 77522 and CPT 77520) should be placed in a different APC than codes for intermediate (CPT 77523) and complex (CPT 77525) radiation therapy. However, it would be inappropriate to return these codes to their previous new technology APCs (0712 and 0712) due to our having sufficient claims data to place them in their own APCs. Therefore, we will place codes for simple radiation therapy (CPTs 77522 and 77520) in APC 0664 and codes for intermediate (CPT 77523) and complex (CPT 77525) therapy in the newly created APC 0650.

Comment: Numerous commenters expressed concern over the movement of HCPC G0173 (Stereo radiosurgery, complete) from APC 0721 (New Technology Level XV $5,000–$6,000) to APC 0663 (Stereotactic radiosurgery), resulting in lower payment. Commenters requested that HCPCS G0173 be returned to APC 0721 (New Technology Level XV $5,000–$6,000) because our current data includes both linear accelerator and multi source treatments.

Response: We agree with commenters and have returned HCPC G0173 (Stereotactic radiosurgery, complete) to APC 0721 (New Technology Level XV $5,000–$6,000). We will review our claims data for next year's proposed rule to determine appropriate placement for all stereotactic radiosurgery procedures.

Comment: Many commenters brought to our attention that G0251 (Stereotactic radiotherapy, multisession) was erroneously omitted from the proposed rule. Commenters asserted that G0251 differs substantially from G0173 and G0243, and they requested that G0251 be reinstated and placed in an APC that pays more than APC 0721 (New Technology Level XV $5,000–$6,000).

Response: We thank the commenters for bringing this to our attention, and we agree that the elimination of G0251 in the proposed rule was in error. However, we do not agree with the

placement of G0251 in an APC that pays more than APC 0721 (New Technology Level XV $5,000–$6,000). Although there are significant fixed costs for all stereotactic radiosurgery procedures, our review of cost data does not show that our current APC assignment for G0251 (APC 713) is inappropriate. We will review the APC assignments for all stereotactic radiosurgery procedures next year when we have 2002 claims data available.

Comment: A commenter expressed concern over the bundling of payments for CPT 77370 (Special medical radiation physics consultation) and CPT 77336 (Continuing medical physics consultation) into code G0242 (Multisource photon stereotactic plan) based on the understanding that G0242 is unrelated to CPT 77370 and CPT 77336. The commenter requested that CPT 77370 and CPT 77336 be unbundled from G0242.

Response: We want hospitals to bill all resources associated with G0242 in one code. G0242 includes the work of a physicist and other staff, therefore it is appropriate that the resources used for CPT 77370 and CPT 77336 remain bundled with G0242. Separate payment for 77370 and 77336 would result in duplicate payment.

Comment: Many commenters expressed concern that FDG PET procedures are moving to a new clinical APC 0667 (Nonmyocardial positron emission tomography) with a payment of $971—a reduction of $404. The commenters asserted that although the proposed rule would continue separate pass-through payment for FDG (in APC 1775), the proposed new payment would not cover the cost of the PET procedure and would undermine access to care.

Response: We agree that our claims data may not accurately reflect the cost of FDG PET procedures.

On June 29, 2001, CMS announced its intention to issue a national coverage determination (NCD) limiting the type of technology that can be used to perform Medicare-covered PET scans. This NCD became effective January 1, 2002. We believe that our claims data includes a significant number of PET scans performed on coincidence cameras that are no longer covered by Medicare. This could have the effect of lowering the median cost as compared to our future claims data that will reflect (due to the NCD) only the use of full-ring or partial-ring PET scanners. For this reason, until we are confident that our claims data reflects the predominant use of dedicated PET scanners, we will continue to pay for FDG PET in APC 714 (New Technology—Level IX $1250–$1500) until further review of claims data for the 2004 final rule.

Comment: A commenter expressed concern about our proposal to reassign digital mammography from New Technology APC 0707 to a clinical APC (0699). Commenters recommended that we retain the assignment to New Technology APC 0707 for 1 more year until further data analysis can be performed.

Response: We disagree with the commenter. Hospitals billed for approximately 7,000 occurrences of digital mammography in 2001, providing us with sufficient data upon which to calculate a median cost.

New Technology APC Issues

Comment: A manufacturer was pleased that we designated endometrial cryoablation as eligible for new technology service APC payment, but was displeased at the delay in reaching our decision as well as the specific new technology service APC in which the service was placed. We proposed to place endometrial cryoablation into new technology service APC 980, which has a payment rate of $1,875. The commenter contended that endometrial cryoablation has similar resource costs as cryoablation of the prostate and should be assigned to new technology service APC 984, at $4,250, which would cover the cost of a cryoablation probe also. It provided a brief cost analysis from a single major medical center.

Response: We assigned endometrial cryoablation into new technology service APC 980 based on cost data submitted.

New Technology APC for Preview Planning Software

Comment: A manufacturer commented on our proposal to reassign the procedure related to Preview Treatment Planning Software (C9708) from its current APC 975, which pays $625, to APC 973, which pays $250. The manufacturer of Preview asserted that its sales records, which it provided, demonstrate that the cost to hospitals of providing Preview support the assignment of APC 975. It contended that we must have based the new APC assignment on faulty claims data.

Response: For the final rule, we had access to a larger number of claims for C9708, and we have moved it back to APC 975.

Comment: A manufacturer was pleased that we designated endometrial cryoablation as eligible for new technology service APC payment, but was displeased at the delay in reaching our decision as well as the specific new technology service APC in which the service was placed. We proposed to place endometrial cryoablation into new technology service APC 980, which has a payment rate of $1,875. The commenter contended that endometrial cryoablation has similar resource costs as cryoablation of the prostate and should be assigned to new technology service APC 984, at $4,250, which would cover the cost of a cryoablation probe also. It provided a brief cost analysis from a single major medical center.

Response: We assigned endometrial cryoablation into new technology service APC 980 based on cost data submitted.

Table 3 below is the final list of Healthcare Common Procedure Coding System (HCPCS) reassignments of new technology procedures.

TABLE 3.—CHANGES IN HCPCS ASSIGNMENTS FROM NEW TECHNOLOGY APCS TO PROCEDURE APCS FOR 2003

HCPCS	Description	2002 SI	2003 SI	2002 APC	2003 APC
19103	Bx breast precut w/device	S	T	0710	0658
33282	Implant pat-active ht record	S	S	0710	0680
36550	Declot vascular device	T	T	0972	0677
53850	Prostatic microwave thermotx	T	T	0982	0675
53852	Prostatic rf thermotx	T	T	0982	0675
55873	Cryoablate prostate	T	T	0982	0674
76075	Dual energy x-ray study	S	S	0707	0288
76076	Dual energy x-ray study	S	S	0707	0665
77520	Proton trmt, simple w/o comp	S	S	0710	0664
77522	Proton trmt, simple w/comp	S	S	0710	0664

TABLE 3.—CHANGES IN HCPCS ASSIGNMENTS FROM NEW TECHNOLOGY APCS TO PROCEDURE APCS FOR 2003—Continued

HCPCS	Description	2002 SI	2003 SI	2002 APC	2003 APC
77523	Proton trmt, intermediate	S	S	0712	0664
77525	Proton treatment, complex	S	S	0712	0664
92586	Auditor evoke potent, limit	S	S	0707	0218
95965	Meg, spontaneous	T	S	0972	0717
95966	Meg, evoked, single	T	S	0972	0714
95967	Meg, evoked, each addl	T	S	0972	0712
C1300	Hyperbaric oxygen	S	S	0707	0659
C9708	Preview Tx Planning Software	T	T	0975	0973
G0125	PET img WhBD sgl pulm ring	T	S	0976	0667
G0166	Extrnl counterpulse, per tx	T	T	0972	0678
G0168	Wound closure by adhesive	T	X	0970	0340
G0173	Stereo radoisurgery, complete	S	S	0721	0663
G0204	Diagnostic mammography digital	S	S	0707	0669
G0206	Diagnostic mammography digital	S	S	0707	0669
G0210	PET img whbd ring dxlung ca	S	S	0714	0667
G0211	PET img whbd ring init lung	S	S	0714	0667
G0212	PET img whbd ring restag lun	S	S	0714	0667
G0213	PET img whbd ring dx colorec	S	S	0714	0667
G0214	PET img whbd ring init colre	S	S	0714	0667
G0215	PET img whbd restag col	S	S	0714	0667
G0216	PET img whbd ring dx melanom	S	S	0714	0667
G0217	PET img whbd ring init melan	S	S	0714	0667
G0218	PET img whbd ring restag mel	S	S	0714	0667
G0220	PET img whbd ring dx lymphom	S	S	0714	0667
G0221	PET img whbd ring init lymph	S	S	0714	0667
G0222	PET img whbd ring resta lymp	S	S	0714	0667
G0223	PET img whbd reg ring dx hea	S	S	0714	0667
G0224	PET img whbd reg ring ini hea	S	S	0714	0667
G0225	PET img whbd ring restag hea	S	S	0714	0667
G0226	PET img whbd dx esophag	S	S	0714	0667
G0227	PET img whbd ring ini esopha	S	S	0714	0667
G0228	PET img whbd ring restg esop	S	S	0714	0667
G0229	PET img metabolic brain ring	S	S	0714	0667
G0230	PET myocard viability ring	S	S	0714	0667
G0231	PET WhBD colorec; gamma cam	S	S	0714	0667
G0232	PET WhBD lymphoma; gamma cam	S	S	0714	0667
G0233	PET WhBD melanoma; gamma cam	S	S	0714	0667
G0234	PET WhBD pulm nod, gamma cam	S	S	0714	0667

3. APC Assignment for New Codes Created During Calendar Year (CY) 2002 and Selected Codes and APC Assignments for 2003

During CY 2002, we created several HCPCS codes to describe services newly covered by Medicare and payable under the hospital OPPS. While we have assigned these services to APCs for CY 2002, we opened the assignments to public comment in the proposed rule. In addition, in the proposed rule, we proposed to create several new HCPCS codes and APC assignments with an effective date of January 1, 2003 and we solicited comments on these proposed codes and proposed APC assignments. Table 4 below includes new procedural HCPCS codes either created for implementation in July 2002, which we intend to implement in October 2002, or which we will implement in January 2003.

Table 4 does not include new codes for drugs and devices for which we established or intend to establish pass-through payment eligibility in July or October 2002.

TABLE 4.—NEW G CODES FOR 2002 AND 2003 FOR WHICH THERE ARE FINAL APC ASSIGNMENTS

Code	Long descriptor	Effective	Final APC	SI
G0245	Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include: 1. The diagnosis of LOPS, 2. A patient history, 3. A physical examination that consists of at least the following elements: (a) Visual inspection of the forefoot, hindfoot, and toe web spaces, (b) Evaluation of a protective sensation, (c) Evaluation of foot structure and biomechanics, (d) Evaluation of vascular status and skin integrity, and (e) Evaluation and recommendation of footwear. 4. Patient education.	7/1/2002	0600	V

TABLE 4.—NEW G CODES FOR 2002 AND 2003 FOR WHICH THERE ARE FINAL APC ASSIGNMENTS—Continued

Code	Long descriptor	Effective	Final APC	SI
G0246	Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a LOPS to include at least the following: 1. A patient history. 2. A physical examination that includes: (a) Visual inspection of the forefoot, hindfoot, and toe web spaces, (b) Evaluation of protective sensation, (c) Evaluation of foot structure and biomechanics, (d) Evaluation of vascular status and skin integrity, and (e) Evaluation and recommendation of footwear. 3. Patient education.	7/1/2002	0600	V
G0247	Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include if present, at least the following: (1) local care of superficial wounds, (2) debridement of corns and calluses, and (3) trimming and debridement of nails.	7/1/2002	0009	T
G0248	Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstrating use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing.	7/1/2002	0708	S
G0249	Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria. Includes provision of materials for use in the home and reporting of test results to physician; per 4 tests.	7/1/2002	0708	S
G0250	Physician review, interpretation and patient management of home INR testing for a patient with mechanical heart valve(s) who meets other coverage criteria; per 4 tests (does not require face-to-face service).	7/1/2002	N/A	E
G0252	PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes).	10/1/2002	0714	S
G0253	PET imaging for breast cancer, full and partial-ring PET scanners only, staging/restaging of local regional recurrence or distant metastases (i.e., staging/restaging after or prior to course of treatment).	10/1/2002	0714	S
G0254	PET imaging for breast cancer, full and partial-ring PET scanners only, evaluation of response to treatment, performed during course of treatment.	10/1/2002	0714	S
G0255	Current perception threshold/sensory nerve conduction test, (sNCT) per limb, any nerve	10/1/2002	N/A	E
G0258	Intravenous infusion during separately payable observation stay, per observation stay (must be reported with G0244).	1/1/2003	0340 Deleted with 90-day grace period	X
G0257	Unscheduled or emergency dialysis treatment for an ESRD patient in a hospital outpatient department that is not certified as an ESRD facility.	1/1/2003	0170	S
G0259	Injection procedure for sacroiliac joint; arthrography	1/1/2003	N/A	N
G0260	Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent and arthrography.	1/1/2003	0204	T
G0256	Prostate brachytherapy using permanently implanted palladium seeds, including transperitoneal placement of needles or catheters into the prostate, cystoscopy and application of permanent interstitial radiation source.	1/1/2003	0649	T
G0261	Prostate brachytherapy using permanently implanted iodine seeds, including transperitoneal placement of needles or catheters into the prostate, cystoscopy and application of permanent interstitial radiation source.	1/1/2003	684	T
G0263	Direct admission of patient with diagnosis of congestive heart failure, chest pain or asthma for observation.	1/1/2003	N/A	N
G0264	Initial nursing assessment of patient directly admitted to observation with diagnosis other than congestive heart failure, chest pain, or asthma.	1/1/2003	0600	S
G0290	Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel.	1/1/2003	0656	E
G0291	Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel.	1/1/2003	0656	E

HCPCS Codes Created During CY 2002

The G codes G0245 through G0250 were created to implement payment for newly covered Medicare services due to national coverage determinations. The G codes G0252–G0255 were established October 1, 2002, as a result of national coverage policies that became effective October 1, 2002. These codes were created to accurately describe the services covered, to ensure that they were reported correctly, to track their utilization, and to establish payment.

We solicited comments on the APC assignment of these services. The codes describing evaluation and management services were assigned to clinic visit APCs containing similar services, and the codes describing procedural services were assigned to new technology APCs or to APCs containing procedures requiring similar resource consumption. Because G0250 is a professional service furnished by a physician, it is not payable under OPPS.

We did not receive any comments on the codes or APC assignments for G0245, G0246, G0247, G0248, G0249, G0250, or G0255. Therefore, we are finalizing them as shown.

We are also finalizing APC assignments for G0252, G0253, and G0254. The comments and responses for these services are discussed elsewhere in this preamble.

We implemented HCPCS code G0258 (Intravenous Infusion(s) During Separately Payable Observation Stay)

effective October 1, 2002, to describe infusion therapy given during a separately payable observation stay. We assigned it to APC 0340 because we believed APC 0340 appropriately accounts for the resources used for infusion during observation. As discussed in section X.B, we received many comments opposing creation of this code. Therefore, we will delete it effective January 1, 2003.

New HCPCS Codes for January 1, 2003, for Which We Proposed APC Assignments in the August 9, 2002 Proposed Rule

In the August 9, 2002, proposed rule, we proposed to create several new HCPCS codes for 2003 to address issues that have come to our attention, to describe new technology procedures, to implement policy proposals discussed in the rule, and to allow more appropriate reporting of procedures currently described by (physician's) current procedural terminology (CPT) (HCPCS Level I) codes. The codes we proposed are as follows:

(1) G0FFF—Bone Marrow Aspiration and Biopsy Services—we proposed to create this code to describe bone marrow aspiration and biopsy performed through the same incision. We proposed to place this code in APC 0003. This code also appears in the proposed rule for the physician fee schedule, published in the June 28, 2002, issue of the **Federal Register** (67 FR 43846). This code would facilitate proper reporting of this procedure.

As discussed under general comments and responses below, we received many comments that objected to the proliferation of G codes for the services for which the CPT or HCPCS level II process could be used to create a code. After review of the comments, we agree that this code should go through the CPT process. Therefore, we have not implemented the G code we proposed. We will instead, submit a code for ''Bone Marrow Biopsy and Aspiration Performed in the Same Bone'' to CPT in time for the 2004 CPT code cycle.

(2) G0257—Unscheduled and Emergency Treatment for ESRD Patients—we proposed this code to facilitate payment for dialysis provided to ESRD patients in the outpatient department of a hospital that does not have a certified ESRD facility. The comments, responses, and final action regarding these services are discussed in section X.F of this rule.

(3) G0259 and G0260—Sacroiliac Joint Injections—we proposed to create these two codes to replace CPT code 27096, Injection procedure for sacroiliac joint, arthrography and/or anesthetic steroid. CPT code 27096 describes two distinct procedures requiring different resource consumption. Moreover, our policy of packaging injection procedures for imaging required packaging of this procedure even when it was used to report injection of a steroid or anesthetic. In these cases, it was appropriately billed without another procedure and should have been payable. Therefore, in order to facilitate appropriate reporting and payment for the procedures described by CPT code 27096, we proposed to create G0259, Injection procedure for sacroiliac joint, arthrography, and G0260, Injection procedure for sacroiliac joint, provision of anesthetic and/or steroid. We proposed to give G0259 status indicator N, and we proposed to assign G0260 to APC 0204.

Comment: Many commenters raised concern over nonpayment for sacroiliac joint injections. The commenter brings to our attention that when a sacroiliac joint injection, CPT code 27096 (Injection procedure for sacroiliac joint, arthrography and/or anesthetic steroid), is performed for anesthetic/steroid purposes, the procedure is not being paid since the costs are only packaged into the arthrography imaging component.

Response: We appreciate this concern and agree with the commenter that payment should be made for sacroiliac joint injections when administered for anesthetic/steroid purposes. Therefore, in order to facilitate appropriate reporting and payment for the procedures described by CPT code 27096 (Injection procedure for sacroiliac joint, arthrography and/or anesthetic steroid), we have created the following new G-codes to replace CPT code 27096: G0259 (Injection procedure for sacroiliac joint, arthrography) and G0260 (Injection procedure for sacroiliac joint, provision of anesthetic and/or steroid). G0259 has been given status indicator N, and G0260 has been assigned to APC 0204.

(4) G0KKK—Prostate Brachytherapy—we proposed this code to implement our policy decision discussed in section III.C.3 of the proposed rule (section IV.E of this rule). As a result of comments we created two new codes G0256 and G0261. See section IV.E. for the discussion of prostate brachytherapy.

(5) G0263 and G0264—Observation Care—we proposed to create these codes to describe observation care provided to a patient who is directly admitted from a physician's office to a hospital for observation care. We discussed these codes in detail in section VIII.B of the proposed rule. Our discussion of the final action, comments, and responses is contained in section X.B of this rule.

(6) G0290, G0291; Drug Eluting Stents—We discuss these codes in the immediately following section.

Drug-Eluting Stents

In the August 9, 2002 proposed rule, we discussed the exceptional circumstances that led us to propose a departure from our standard OPPS payment methodology as we have done under the inpatient PPS for Federal fiscal year (FY) 2003 (67 FR 50003–50005). We made this unusual proposal to ensure consistent payment for drug-eluting stents in both the inpatient and outpatient settings; to ensure that hospital resources are not negatively affected by a sudden surge in demand for this new technology if FDA approval is received; and to ensure that Medicare payment does not impede beneficiary access to what appears to be a potentially landmark advance in the treatment of coronary disease. Consistent with the special approach we implemented in the inpatient PPS final rule, we proposed to create two new HCPCS codes and a new APC that may be used to pay for the insertion of coronary artery drug-eluting stents under the OPPS to be effective if these stents receive FDA approval for general use. Of course, as with other new procedures, FDA approval does not mean that Medicare will always cover the approved item. Medicare coverage depends upon whether an item or service is medically necessary to treat an illness or injury as determined by Medicare contractors based on the specifics of individual cases.

The new HCPCS codes that we proposed are as follows:

G0290—Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel

G0291—Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel

We proposed to assign G0290 and G0291 to new APC 0656, Transcatheter Placement of Drug-Eluting Coronary Stents, with a status indicator of T.

To establish a payment amount for the proposed new APC, we proposed to apply the same assumptions that we used in establishing the weights for diagnosis-related group (DRG) 526 (Percutaneous Cardiovascular Procedure with Drug-Eluting Stent with AMI) and DRG 527 (Percutaneous Cardiovascular Procedure With Drug-Eluting Stent Without AMI) as described in the final

rule implementing the FY 2003 inpatient PPS. That is, we assume a price differential of approximately $1,200 when drug-eluting stents are used. We assumed an average of 1.5 stents per procedure, and we proposed to add $1,200 to the median costs established for APC 0104 based on 2001 claims data to determine the payment rate for APC 656. We proposed to calculate a relative payment weight and payment rate for APC 0656 in accordance with the methodology that we discuss in section III.B. of this preamble.

We proposed to implement payment under APC 0656 effective April 1, 2003, consistent with the effective date for implementation of the drug-eluting DRGs under the OPPS and contingent upon FDA approval by that date. If the FDA grants approval prior to April 1, 2003, hospitals would be paid for insertion of coronary artery drug-eluting stents under APC 104. Such claims may qualify for outlier payments.

We proposed to establish the new HCPCS codes and APC group for coronary artery drug-eluting stents to allow close tracking of the utilization and costs associated with these services. In the proposed rule, we invited comments on this proposed methodology for recognizing the additional costs of drug-eluting stents under the OPPS.

Comment: All of the commenters who addressed our payment proposal for drug-eluting stents supported our taking proactive steps to create an APC for this new technology in anticipation of FDA approval by April 2003. However, most of the commenters expressed concern about the level of payment proposed for APC 656, stating that $1,200 significantly understates the added cost of the drug-eluting stents. One commenter suggested that indications from the market are projecting a cost of $2,000 per stent. Another commenter cited vendors who indicate that drug-eluting stents will cost 3 times the cost of the current stent for an approximate cost of $3,360 each. Several commenters stated that the incremental cost between a bare metal and a drug-eluting stent is expected to be $2,000. Two commenters urged us to set the rate for APC 656 based on the actual price difference between the current and drug-eluting stents, and one commenter recommended setting the initial payment amount at a level that is 60 percent above the probable hospital acquisition cost. One commenter asked why we added $1,200 to APC 656 rather than $1,800. The basis for this request was that the incremental payment for inpatient care was $1,800 for an average of 1.5 stents per procedure.

Response: To establish a payment rate for APC 656, we proposed to add $1,200 to the median cost of stent insertion procedures in APC 104, based on assumptions that we applied to establish the weights for DRGs involving drug-eluting stents under the inpatient PPS. Based on the median cost established for APC 104 using the 2001 claims data that were reflected in the August 9, 2002 proposed rates, we determined that an additional $1,200 would offset the incremental cost of an average of 1.5 drug-eluting stents per procedure.

We do not agree that the incremental payment should be $1,800. Although it is true that 1.5 stents are typically placed per procedure, it is rare for two stents to be placed in one coronary artery in an outpatient setting. Furthermore, hospitals can bill under the OPPS a separate code for each vessel in which a stent is placed, unlike the inpatient PPS. Because hospitals will in most cases be able to report each stent placement separately in the outpatient setting, making an incremental payment of $1800 would significantly overpay for each stent.

As we explain elsewhere in this preamble, the payment rates that this final rule implements are based on more current data than those that were available when we set the rates proposed in the August 9, 2002 rule. The rates in this final rule also reflect adjustments intended to level the transition from rates based on pre-OPPS data and estimated pass-through device and drug costs to rates based entirely on OPPS data that reflect actual device and drug costs reported by hospitals.

Comment: One commenter expressed concern about our expectation that a new technology must ''transform'' medical care and be the object of substantial demand in order to justify making an exception to our standard OPPS payment methodology. The commenter believes that our rationale for making an exception for drug-eluting stents establishes an almost unattainable threshold for other technologies to reach in order to receive similar treatment in the future. Conversely, another commenter expressed concern that by establishing codes and payment rates for drug-eluting stents, we are setting a precedent that will likely increase the pressure to create new temporary codes for non-breakthrough technologies. This commenter encouraged us to maintain highly selective criteria when creating new codes for new technologies in the future.

Response: As we explain at length in the August 9, 2002 proposed rule, we believe that drug-eluting stents are potentially a revolutionary approach to the treatment of coronary disease. Ordinarily, we would expect a new technology like the drug-eluting stent to qualify for a pass-through payment or for payment under a new technology APC.

However, because the drug-eluting stent does not meet the criteria established for these two methods of payment for new technology under the OPPS, we were compelled to seek an alternative approach in order to ensure beneficiary access to this extraordinary new treatment, once it receives FDA approval, without placing an extraordinary burden on hospital resources. We expect that either a pass-through payment or assignment to a new technology APC will, in the overwhelming preponderance of cases, provide adequate and timely payment under the OPPS for new technology. We agree with the commenter who supported maintaining highly selective standards when establishing codes for new technology. The threshold for such an approach must be exceptionally high and applicable only in the most extraordinary and unusual cases.

Comment: One commenter asked that we clarify how we will adjust the 2003 OPPS payment rates if FDA approval is not given for drug-eluting stents by April 1, 2003. The commenter is concerned about the adverse effect on the rates for other services that would result from our having recalibrated and scaled the relative payment weights for all services, taking into account additional payment for drug-eluting stents that turns out not to be an expenditure.

Response: We have reviewed the impact of the drug-eluting stents on the total recalibration exercise and determined that excluding the additional allowance for the drug-eluting stents would not result in a significant redistribution of funds for other services if FDA approval were not issued by April 1, 2003, triggering payment under the OPPS. We estimated that slightly fewer than one-third of the cases paid under APC 104 (approximately 5,400 procedures) would be performed using drug-eluting stents during the three quarters of 2003 when payment would be made for APC 656, assuming FDA approval is issued by April 1, 2003. Payment for the use of drug-eluting stents represents approximately 0.17 percent of the total APC weights. Restoration of these payments to the pool of weights for other services would not measurably

change the weights of the other APCs. Therefore, we would not revise the 2003 APC weights if payment for drug-eluting stents were not allowed beginning April 1, 2003.

Comment: One commenter expressed concern that the general use of data from other countries to set the national payment rate for a new device in the absence of hospital claims and cost data raises long term issues regarding the impact this approach would have on manufacturers' investment and pricing strategies, both abroad and in the United States. The commenter recommended that we consider these issues in more depth.

Response: We respond to this issue in our discussion of MedPAC comments in section XI.

Comment: One commenter recommended that we carefully monitor the use of APCs for which the national payment rate is established based on pricing in countries other than the United States and the costs reported by hospitals for those APCs. Another commenter stated that the new HCPCS codes for the drug-eluting stent procedures should be temporary and that we should ask the CPT Editorial Board to develop national CPT codes as soon as possible.

Response: As we indicated in the August 9, 2002 proposed rule, we intend to closely track the utilization and costs associated with the drug-eluting stents. We established the G-codes for the use of drug-eluting stents precisely in order to permit us to collect these data. However, the cost data taken from hospital claims associated with the use of the drug-eluting stents will ultimately be incorporated into the current CPT codes for coronary stent placement. We believe that the current CPT codes describe the procedure adequately and that separate permanent codes specific to the use of drug-eluting stents are not necessary based on the expectation that drug-eluting stents will eventually become the standard of care.

Effective for services furnished on or after April 1, 2003, contingent upon FDA approval of the drug-eluting stents, we are implementing payment under APC 656, Transcatheter Placement of Drug-Eluting Coronary Stents, for two temporary HCPCS codes:

G0290 Transcatheter placement of a drug-eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel.

G0291 Transcatheter placement of a drug-eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel.

Note that Table 6 and Addendum B show status indicator E for HCPCS codes G0290 and G0291 since payment under these codes will not be effective before April 1, 2001. However, we include the APC for drug eluting stent procedures (APC 0656) in Addendum A with the payment rate and status indicator of T to identify how these new codes will be paid once they are implemented.

If the FDA grants approval before April 1, 2003, hospitals will be paid for placement of drug-eluting stents under APC 104. If the FDA does not grant approval by April 1, 2003, we will announce a new effective date for APC 0656 and for HCPCS codes G0290 and G0291 by Program Memorandum.

G codes for Outpatient Services Under National Clinical Trials

We have created three new G codes for use in reporting services furnished in hospital outpatient departments under national clinical trials: G0292 Administration(s) of experimental drug(s) only in a Medicare qualifying clinical trial (includes administration for chemotherapy and other types of therapy via infusion and/or other than infusion), per day.

G0293 Noncovered surgical procedure(s) using conscious sedation, regional, general or spinal anesthesia in a Medicare qualifying clinical trial, per day.

G0294 Noncovered surgical procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day.

On September 19, 2000, Medicare issued a national coverage decision stating that Medicare will pay for the routine costs of clinical trials. This policy is published as section 30–1 of Medicare's Coverage Issues Manual. Because the experimental intervention is not covered but items and services required solely because of the intervention are covered, we needed to identify ways to properly code for and pay for the routine costs when delivered in a hospital outpatient department.

We believe that to accurately pay for the covered services associated with the administration of drugs as part of a clinical trial, we need to create a new code to allow for correct billing and payment for routine costs, as defined by the national coverage determination. Therefore, the code G0292, ''Administration(s) of experimental drug(s) only in a Medicare qualifying clinical trial (includes administration for chemotherapy and other types of therapy via infusion and/or other than infusion), per day,'' should be billed when only experimental drugs are administered as part of a Medicare qualifying clinical trial. When an experimental drug is being administered in conjunction with payable drugs or on the same day as payable drugs, G0292 should not be used. Instead, the appropriate drug administration code should be billed.

There are also procedures that may be performed in the hospital outpatient department as part of a qualifying clinical trial. Because the intervention is not covered under Medicare's clinical trial policy, we need a mechanism to pay the hospital for its covered fixed costs associated with providing the service under the clinical trial. We have created two codes to allow for correct billing of procedures performed as the focus of qualifying clinical trials, G0293 and G0294. G0293 is defined as ''Noncovered surgical procedure(s) using conscious sedation, regional, general or spinal anesthesia in a Medicare qualifying clinical trial, per day,'' and G0294 is defined as ''Noncovered surgical procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day.''

All three of these codes are for OPPS use only. Other provider types may not bill these codes.

The interim APC assignments for G0292, G0293, and G0294 are APC 0708, 0710, and 0707, respectively. The status indicator for these three codes is S. As discussed below, this APC assignment is subject to comment during the comment period discussed in section I of this rule.

General comments on creation and use of G codes

Comment: Several commenters were concerned about the creation of G codes with long descriptors that appear complex and specific to OPPS rules. In addition, we received comments indicating that the hospital coding community was less familiar with G codes and requesting that CMS consider other existing code sets.

Response: Prior to the creation of any G code, we examine alternative mechanisms for implementing coverage and payment policy in a timely fashion. In the event no other appropriate mechanism exists, we create a G code to allow accurate payment given applicable statutory and regulatory requirements. After the creation of a G code, we work with the American Medical Association's Current Procedural Terminology (CPT) Editorial Panel whenever possible to create a replacement CPT code. We are deleting 25 G codes this year as a result of this process. However, there are instances

where G codes cannot be converted to CPT codes due to the unique nature of the statutory and regulatory requirements. In these situations, we work to educate the provider community as to the appropriate use of these codes. Part of this educational effort includes the development of comprehensive descriptors at the time the G code is created.

Comment: Two commenters indicated they would like to see a shorter timeframe between the FDA approval for a new drug and the development of a HCPCS code for that drug.

Response: The FDA approval process is one source of information we use in reviewing new drugs. However, the FDA process does not address the statutory and regulatory requirements of the Medicare program. We perform our review of new drugs as expeditiously as possible given these requirements. We are conscious of the need to streamline this process and we will continue to seek ways to do so.

Public Comments on Interim APC Assignments for Codes New for 2003

As discussed in section I, we are accepting public comment on the interim APC assignments for the new codes shown in Addendum A with the indicator NI. These codes are new for 2003 and the APC assignment was not subjected to public comment in the August 9, 2002 proposed rule. We are not accepting comment on APC assignments that were proposed in the August 9, 2002 proposed rule and are being shown as NF in Addendum B since they have already been subjected to public comment and are made final in this rule.

Comment: Several commenters expressed concern about the increasing frequency of G codes issued by CMS. Commenters asserted that, in the interest of coding standardization, clarity, and accuracy, G codes should be developed only as a last resort. Commenters also stated that G codes sometimes overlap or duplicate other code sets. One commenter recommended a single, standardized process for establishment of temporary HCPCS Level II codes, ensuring that a duplicate or overlapping code is not anticipated in another coding set (for example, CPT).

Response: We agree that, where appropriate, G codes should be temporary. Unfortunately, it is sometimes necessary to develop G codes to accommodate changes in legislation, regulation, coverage, and payment policy. Not only is the timetable for such changes inconsistent with the timetable for CPT publication, but frequently these changes must be made on a quarterly basis.

In 2002, CMS and CPT staff, working together, reviewed all existing G codes and agreed to transition over 20 of them to CPT codes. Therefore, for 2003 many G codes will be deleted in favor of newly created CPT codes. We believe that an annual review of G codes by CMS and CPT staff is the best way to determine which G codes should be transitioned to CPT codes and the process to use for such a transition. Therefore, we plan to continue working with CPT staff on an annual basis to continue transitioning existing G codes to CPT codes. We believe such an annual, comprehensive review will address the commenters' concerns. However, we do wish to emphasize that CMS, where appropriate, does consult with interested providers prior to the creation of G codes in order to facilitate coding clarity and minimize the coding burden on hospitals.

4. Other Public Comments on APC Assignments and Payment Rates

Comment: One commenter asked us to create three new tech APCs for cardiac resynchronization therapy, or, alternatively, to establish a new tech APC payment for placement of the left ventricular lead used in cardiac resynchronization therapy.

Response: We have placed the CPT codes for left ventricular lead placement in new tech APCs. We believe the APC placement accounts for the cost of the procedure and for the lead. The cost of the guidewires and catheters used in the procedure will be captured in the code used to report placement of the pacemaker or cardioverter defibrillator and other leads.

Comment: Several commenters were concerned about bundling payment of radiopharmaceuticals into procedures and about payment reductions for myocardial perfusion scanning.

Response: Payment for most myocardial perfusion scans will increase in 2003 and the payment reduction for scans in APC 666 is commensurate with the costs of performing those procedures. The issue of packaging radiopharmaceuticals is discussed elsewhere in this preamble.

Comment: A commenter expressed concern about CMS's decision to discontinue the pass-through category C1780 (New Technology Intraocular Lens (IOLs)). The commenter stated that the proposal to eliminate this code from pass through status and separate payment contradicts existing regulations.

Response: We do not agree that our proposal contradicts existing regulations. We believe the commenter is referring to § 141 (b) of the Social Security Act Amendments of 1994 (Public Law 103–432) that requires us to implement a process under which interested parties may request a review of the appropriateness of payment for IOLs furnished by ambulatory surgical centers (ASCs). In compliance with this statutory change, we published regulations concerning payment for IOLs in ASCs (42 CFR 416). Those regulations do not apply to the payment for such lenses furnished to patients of hospital outpatient departments. As described elsewhere in the final rule, the cost of IOLs, along with the costs of other sunsetting pass through devices, is reflected in the median cost and thus the payment for the procedures with which IOLs are used.

Comment: A commenter asserted that the current description of HCPCS code J2790 is flawed. According to the commenter, the description of ''1 dose package'' does not accurately describe the two sizes of dosage units available in the marketplace for different indications (50 mcg and 300 mcg). The commenter expressed hope that an application for new HCPCS codes would be approved, and the commenter also requested that we establish separate payment rates for this product based upon the distinction between the two dosages. The commenter noted that current ''Redbook'' average wholesale price (AWP) for the 50 mcg dose is $53.90; for the 300 mcg dose, it is $126.14.

Response: We reviewed the hospital charge data upon which the payment amount for this code must be based. In the absence of separate codes for two different product sizes, we are unable to determine a separate median cost per encounter for the two sizes. We can only base our determination about this product on existing data that represents the current descriptor of this code. We note that, in using the latest set of OPPS claims data available for the final rule, the median cost per encounter of this code was below the $150 threshold. Therefore, this code will be packaged in 2003.

Comment: A commenter requested that we create new HCPCS codes, one for digital-based computer-aided detection (CAD) with screening mammography and one for digital-based CAD with diagnostic mammography.

Response: When the computer-aided detection codes were originally assigned, there was minimal use of CAD in conjunction with direct digital mammography. The current descriptors of both HCPCS G0236 and CPT code 76085 do not explicitly state that these

services can be billed in conjunction with either direct digital images or standard film images converted to digital images for this reason. We agree with the commenter that use of CAD with direct digital images should be reportable. Therefore, we have revised the descriptor of HCPCS code G0236 to include conversion of both direct digital images and standard film images converted to digital images. Additionally, we will request that the CPT editorial panel review the current definition associated with the screening computer-aided detection code (CPT code 76085) for future revision. Until any such revision is made to CPT code 76085, hospitals should use CPT code 76085 for reporting application of CAD to both direct digital screening images and standard film images.

The descriptor for G0236 has been revised to read as follows: digitalization of film radiographic images with computer analysis for lesion detection, or computer analysis of digital mammogram for lesion detection, and further physician review for interpretation, diagnostic mammography (list separately in addition to code for primary procedure). We believe that we have sufficient claims data to use in assigning digital mammography to an APC.

Comment: Several commenters expressed concern over the payment rate reduction for CPT 52353 (Cystoureteroscopy with lithotripsy) in APC 0163 (Level IV Cystourethroscopy and other genitourinary procedures). Commenters also requested that we place CPT 52353 in APC 0169 (Lithotripsy).

Response: Movement of CPT 52353 to APC 0169 would result in APC 0169 no longer being clinically homogenous, therefore CPT 52353 (Cystoureteroscopy with lithotripsy) will remain in APC 0163 (Lithotripsy) with other similar procedures.

Comment: Several commenters brought to our attention that placing CPT 52234 (removal of small tumors) and CPT 52235 (removal of medium tumors) in APC 163 (Level IV Cystourethroscopy) instead of APC 0162 (Level III Cystourethroscopy) would adversely affect the payment rate for APC 0163, which contains several more costly procedures. Furthermore, commenters stated that it seemed illogical for CPT 52234 (removal of small tumors) and CPT 52235 (removal of medium tumors) to be placed in APC 0163 while CPT 52224 (removal of minor tumors) and CPT 52240 (removal of large tumors) were placed in APC 0162 (Level III Cystourethroscopy). These commenters requested that these four codes be placed together in APC 0162 (Level III Cystourethroscopy).

Response: We agree with commenters and have placed CPT codes 52234 and 52235 in APC 0162 (Level III Cystourethroscopy). This result is a significant increase in payment for APC 0163 while maintaining an appropriate payment rate for CPT codes 52234 and 52235.

Comment: A commenter stated that APC 0100 (Cardiac stress tests) carries a proposed payment rate of $69.69, which the commenter believes does not sufficiently cover the cost of CPT 93025 (Microvolt t-wave alternans). The commenter requested that CPT 93025 be assigned to an APC that pays in the $250 range.

Response: CPT 93025 (Microvolt t-wave assessment) is frequently performed simultaneously with CPT 93017 (Cardiovascular stress test) (that is, the patient is placed on a treadmill once and data for the stress test and Microvolt t-wave alternans are obtained simultaneously), achieving significant economies of scale. Therefore we will keep CPT 93025 (Microvolt t-wave assessment) in APC 0100 (Cardiac stress tests). However, we will review this request again next year when we have more claims data for 93025.

Comment: We received several comments urging that CPT 52647 (Laser surgery of prostate) be placed in a higher paying APC than APC 0163 (Level IV Cystourethroscopy and other genitourinary procedures) in order to cover the cost of a new laser source involved in this procedure.

Response: We have significant claims for this procedure. Any costs associated with new technology developed to perform this procedure should be reflected in future claims data, insofar as the new technology is used, and will be reflected in our updated payment rates. Because we have sufficient claims data indicating the appropriate placement of this service is in APC 0163, CPT 52647 (Laser surgery of prostate) will remain in APC 0163.

Comment: A commenter urged that we maintain a separate APC for items currently billed under C1784 (Ocular device, intraoperative, detached retina). The commenter stated that separate coding and payment would ensure that the procedure groupings maintain their clinical homogeneity and remain similar with respect to resource consumption.

Response: We do not agree that a separate APC for items currently billed under C1784 (Ocular device, intraoperative, detached retina) is necessary to maintain clinical homogeneity or to remain similar with respect to resource consumption. Therefore, items currently billed under C1784 will not remain in a separate APC. However, we will present this issue to the Advisory Panel on Ambulatory Payment Classification Groups (the APC Advisory Panel) next year for further review.

Comment: A commenter expressed concern over the movement of CPT 15000 (surgical debridement) from APC 0026 (Level III Skin repair) to APC 0025 (Level II Skin repair) due to the consolidation of these APCs. The commenter believed that if CPT 15000 and CPT 15342 (Cultured skin graft, 25 cm) were placed in the same APC that separate payment would not be made for both procedures.

Response: The commenter is incorrect. Separate payment will be made for both procedures even if they are in the same APC. Because this APC has a status indicator of ''T,'' payment of the full APC amount will be made for the first procedure and 50 percent of the APC amount will be paid for the second procedure. Furthermore, we believe that the codes within APC 0025 are clinically homogeneous and do not violate the 2 times rule. Therefore, we will not move either of these procedures into a different APC.

Comment: Several commenters stated that autonomic nervous system (ANS) services (HCPCS 95921 and 95922) are incongruent with the services grouped in APC 0218. The commenter asserted that ANS tests are more appropriately grouped in APC 0216 when evaluated on the basis of complexity and resources used.

Response: The APC Advisory Panel reviewed this issue and recommended that we move HCPCS 95921 and 95922 to APC 0216 only if our claims data supported such a move. Since our claims data did not support such a move, HCPCS 95921 and 95922 will remain in APC 0218. However, we will present this concern to the APC Advisory Panel again next year.

Comment: A commenter expressed concern over the combination of skin tests and miscellaneous red blood cell tests in APC 0341. The commenter asserted that the services within this group cannot be considered comparable with respect to the resources used. The commenter recommended the creation of a new APC titled, ''Miscellaneous Red Blood Cell Tests'' and suggested that the new APC contain the following HCPCS codes: 86880, 86885, 86886, 86900, and 86901.

Response: We do not agree with the commenter's assertion that the skin tests and miscellaneous red blood cell tests in APC 0341 are not comparable with respect to the resources used. However,

we will present this issue to the APC Advisory Panel.

Comment: A commenter asserts that HCPCS 86915 (Bone marrow/stem cell prep) does not fit within APC 346 (Level II Transfusion Laboratory Procedures) and should be moved to the highest paying Transfusion Laboratory Procedures APC 347(Level III Transfusion Laboratory Procedures). Similarly HCPCS 86932 (Frozen blood freeze/thaw) is more properly categorized with its sister codes (HCPCS 86930 and 86931) in APC 347.

Response: We thank the commenter and agree that CPT code 86915 (Bone marrow/stem cell prep) is not appropriately placed in APC 0346 (Level II Transfusion Laboratory Procedures). Therefore, we have moved HCPC 86915 to APC 0110 (Transfusion). This change maintains the clinical homogeneity of APC 110 and allows a more appropriate payment for CPT code 86915. We also agree with the commenter that CPT code 86932 is more appropriately assigned to APC 0347 based on resource consumption; therefore, we have assigned HCPC 86932 to APC 0347.

Comment: Several commenters asserted that the placement of all prosthetic urological procedures and devices in APC 0182 (Insertion of penile prosthesis) does not adequately reflect the difference in cost between inflatable and non-inflatable penile prostheses. These commenters suggested that CPTs 54401, 54405, and 54410 (codes for inflatable penile prosthesis) be separated from CPTs 54400, 54402, and 54416 (codes for insertion of penile prosthesis) and that the status indicator for APCs 0182 (Insertion of penile prosthesis) and 0179 (Insertion of artificial urinary sphincters) be changed from ''T'' to ''S.''

Response: To the extent that no facility specializes in implanting inflatable penile prostheses, the APC payment should, on average, be appropriate. Therefore, we will not make any changes in APC 182 at this time. However, we will present this issue to the APC Advisory Panel next year. In addition, the status indicator for APCs 0182 (Insertion of penile prosthesis) and 0179 (Insertion of artificial urinary sphincters) will remain a ''T.'' These APCs will rarely, if ever, be reported with a higher paying APC and thus rarely subject to reduction.

Comment: Several commenters were concerned about the large reduction in payment for APC 0222 (Implantation of Neurological Device) and APC 0225 (Implantation of Neurostimulator). They suggested that we continue the use of pass through codes or use manufacturer submitted device cost data, or hospital invoice data, to determine payment rates for these procedures. One commenter also suggested creating a new APC specifically to capture the costs of one brand of devices.

Response: We are also concerned about the payment reduction to these APCs (and other APCs) and have taken steps to address these reductions. Such steps are discussed elsewhere in this rule. For these APCs, we developed relative weights using only claims that contained C codes for devices and in addition we limited the absolute payment reduction. Furthermore, because APCs 0022 and 0225 may be billed together, we have changed the status indicator of APC 0225 to ''S.'' This means that APC 0225 will not be subject to a 50 percent reduction in payment when billed with APC 0222. We believe that the measures we have taken should address the concerns of the commenters.

Comment: Several commenters agreed with our proposal to make separate payment for radiological guidance procedures.

Response: We thank these commenters and are finalizing our proposal.

Comment: One commenter, who performs digital reconstruction of computed tomographic angiography images, stated that the claims data upon which we based our proposed payment rate for C9708 was flawed and that we should use other data sources in determining a payment rate for this code.

Response: In developing the final rule, we had access to a larger number of claims for C9708 and have concluded our proposed payment rate was inappropriate. Accordingly, we will not finalize our proposal, and C9708 will continue to be paid in APC 0975.

Comment: One commenter requested that guidance be provided on proper use of codes for strapping and casting (APCs 58 and 59).

Response: We agree with the commenter and will work with appropriate experts to provide such guidance. In view of the similar costs for all of these procedures in our current data, we will combine these two APCs (as we proposed), as this is administratively easier for hospitals.

Comment: One commenter disagreed with our proposal to combine APCs 0043 and 0044, as more work is involved in treating a fractured leg than a fractured toe.

Response: Our claims data indicates that the hospital resources involved in all of these procedures are very similar. Therefore, we are finalizing our proposal.

Comment: One commenter agreed with our moving all procedures in APCs 0144 and 0145 into APC 0147 but disagreed with our moving CPT code 46600 (diagnostic anoscopy) into APC 0340.

Response: We disagree. We had a substantial number of single procedure claims for CPT 46600, and the median cost for CPT 46600 makes it appropriate for placement in APC 0340. We are finalizing our proposal.

Comment: One commenter objected to our placement of impedence cardiography in APC 0099. The commenter stated that even though APC 0099 was clinically homogeneous, the resources required for impedence cardiography were greater than the resources required to perform other procedures in the APC.

Response: We disagree. The resources used for the procedures in this APC are similar, and it is clinically homogeneous. We are not making any changes in this APC at this time.

Comment: One commenter requested that we move CPT code 95955 (EEG during non intracranial surgery) to APC 213 and that we move CPT code 95904 (Sensory nerve conduction) to APC 0218.

Response: We are not making any changes at this time because our claims data indicates that these procedures are appropriately placed. However, we will present these concerns to the APC Advisory Panel.

Comment: One commenter requested that we move CPT code 0009T (Endometrial cryoablation) to APC 0984 because it should have a payment rate similar to prostate cryoablation (CPT code 55873).

Response: We have placed CPT code 0009T in APC 0980. Based on the information that we have reviewed, we believe that is an appropriate assignment. CPT 0009T is a significantly shorter procedure than CPT 55873 and requires the use of fewer resources. The main cost of CPT 0009T is a disposable probe, the cost of which is appropriately accounted for in APC 0980.

Comment: One commenter requested that we change the status indicator for CPT code 92974 (Coronary brachytherapy) to S.

Response: We are not making any changes at this time, but we will present this to the APC Advisory Panel next year to obtain its input.

Comment: A commenter requested that we move CPT code 57288 (Sling operation for stress incontinence) from APC 202 into its own APC. This is because it is the only procedure in the

APC that requires use of a device. The commenter also believed our claims data was flawed and did not reflect the true cost of the sling used for the procedure. The commenter also asked us to create a special APC payment for the sling.

Response: We are not making any changes at this time but will present this to the APC Advisory Panel. We note that we had many single procedure claims for 57288 and that 57288 was by far the most common procedure performed in APC 202. This means that 57288 determined the payment rate for the APC. Therefore, moving 57288 into its own APC would not change its payment rate. Furthermore, we do not create APCs for devices.

Comment: Two commenters were concerned about reduced payment for echocardiography.

Response: Review of payment rates for echocardiography does not show a significant decrease in payment from 2002 for the most commonly performed echocardiograms. The reduction in payment for echocardiograms in APC 671 appropriately reflects the costs of performing those procedures.

Comment: One commenter asked us to clarify the payment rate for Zevalin.

Response: As discussed elsewhere in this rule we have created G codes that describe the diagnostic and therapeutic administration of Zevalin. These two G codes are placed in APCs with payment rates that account for the procedure and the cost of Zevalin. We will use claims data to update the payment rates of these services when such data becomes available.

Comment: One manufacturer of medical devices submitted comments on a large number of APCs (76, 81, 83, 85, 86, 87, 93, 109, 141, 147, 151, 163, 229, 656, and 670). In general the commenter was concerned about seeming violations of the two times rule, use of improperly coded claims, lack of use of multiple procedure claims, and our use of medians to determine payment rates. The commenter also asked us to use outside cost data in setting payment rates and made some specific requests to move codes to differentAPCs.

Response: Many of this commenter's concerns have been addressed in other responses to APC issues. We did use properly coded claims where appropriate. Specifically, for procedures that required use of a device we only used claims that contained C codes. We also took other measures to mitigate steep reductions in payment for device related APCs and we increased the number of claims we used to set payment rates (as discussed in the proposed rule). We believe that many of the commenter's concerns have been addressed by these measures. However, we will review these comments and present several of the specific requests concerning APC changes to the APC Advisory Panel.

Comment: We received many comments from physicians, freestanding breast imaging centers, and others who believed that the proposed OPPS payment amounts for percutaneous breast biopsy (CPT codes 19102 and 19103) would affect the payments made for physician services and in freestanding breast imaging centers and who objected to reduced payments to physicians and to freestanding breast imaging centers.

Response: These commenters are mistaken. The proposed rates affect only hospital outpatient department payment. Payment to physicians and to freestanding facilities is addressed in the Physician Fee Schedule.

Comment: We received comments from hospitals and others who understood that the proposed payments would be limited to hospital outpatient department services. Some of these commenters indicated that the proposed payments for percutaneous breast biopsy (CPT codes 19102 and 19103) would be substantially below payments to hospitals for open breast biopsy (CPT code 19101) and that the proposed rule proposed reductions in payment for percutaneous breast biopsy while it proposed increases in payment for open breast biopsy. They believe that the proposed payment changes would create incentives for performing open breast biopsies instead of less invasive procedures such as percutaneous biopsies. This may result, they asserted, in an increased frequency of open breast biopsies and a decreased frequency of percutaneous breast biopsies, resulting in poorer quality of care and increased costs to Medicare and to beneficiaries. One commenter believed that our claims data do not appropriately account for the costs of CPT code 19103 because CPT code 19103 was a new CPT code in 2001 and hospitals were slow to transition from using CPT code 19101 for these procedures.

Response: We thank the commenters for their comments. We note that CPT codes 19102 and 19103 are never performed alone. They are always performed, at minimum, in conjunction with an imaging guidance procedure. Therefore, the true payment rate for CPT codes 19102 and 19103 is the sum of the APC payments for CPT codes 19102 or 19103 and of the APC payments for procedures billed with CPT codes 19102 and 19103. In order to determine the true payments for these procedures, we examined our claims data and determined the most common combination of CPT codes billed when CPT codes 19102 and 19103 were on the claim. Our claims data verified that CPT codes 19102 and 19103 are rarely performed alone.

Furthermore, we looked at the 10 most frequent combinations of codes billed with CPT codes 19102 and 19103 and summed the proposed APC payments that would be made for these combinations of codes. This represents the true Medicare payment for CPT codes 19102 and 19103. For CPT code 19102 (for which the proposed rule proposed payment under APC 0005 of $157.01), total payment by Medicare would range from $181.45 to $549.16 when the 10 most common combinations of services are provided. Similarly for CPT code 19103 (for which the proposed rule proposed payment under APC 0658 of $289.69), total payment by Medicare would range from $532.05 to $681.84. These combination totals are less than the proposed payment for open breast biopsy (APC 0028, CPT codes 19105, 19120 and 19125, for which we proposed to pay $908.04); however, as the commenters themselves asserted, the resources required for an open surgical procedure are greater than those used for a percutaneous procedure. We agree with the commenters that the costs to the Medicare program of an open breast biopsy are greater than the cost of a percutaneous biopsy. We also believe that the relative total payment rates, as discussed above, for open and percutaneous procedures are appropriate.

With regard to hospital miscoding, even if hospitals took time to transition from using CPT code 19101 to CPT codes 19102 and 19103, the cost data for CPT codes 19102 and 19103 should be accurate. While it is possible that the cost data for CPT code 19101 could be high as it may include some percutaneous procedures, this would not be true for cost data from CPT codes 19102 and 19103. Further, we would note that each of CPT codes 19102 and 19103 were reported over 20,000 times by hospital outpatient departments and that we had several thousand single claims for each code upon which to base relative weights.

We do not believe that the proposed payments will create incentives to perform inappropriate open breast biopsies. We believe that physicians will select the procedure that best meets the needs of the patient and that the hospital will provide the services

needed to support the procedure that the physician provides.

5. Procedures That Will Be Paid Only as Inpatient Procedures

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. 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 we have already moved off the inpatient list.

We last updated the inpatient list in the November 30, 2001 final rule. As we discuss in section II.A.2 above, the APC Panel at its January 2002 meeting reviewed certain procedures on the inpatient list for which we had received requests that they be made payable under the OPPS. As the Panel members recommended, we solicited comments and further information about all of these procedures except for CPT code 47001, which they recommended to be removed from the inpatient list.

In addition to considering the comments of the APC Panel, we compared procedures with status indicator ''C'' (status indicator ''C'' is assigned to inpatient procedures that are not payable under the OPPS) to the list of procedures that are currently on the ambulatory surgical center (ASC) list of approved procedures, to procedures that we proposed to add to the ASC list in a proposed rule published in the **Federal Register** on June 12, 1998 (63 FR 32291), and to procedures recommended for addition to the ASC list by commenters in response to the June 12, 1998, proposed rule. We concluded that it was appropriate to propose removal of procedures from the OPPS inpatient list that are being performed on an outpatient basis and/or that we had determined could be safely and appropriately performed on a Medicare beneficiary in an ASC under the applicable ASC rules, which are set forth in 42 CFR 416.22. Therefore, we proposed to add the following criteria for use in reviewing procedures to determine whether they should be removed from the inpatient list and assigned to an APC group for payment under the OPPS:

- We have determined that the procedure is being performed in numerous hospitals on an outpatient basis; or
- We have determined that the procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or proposed by us for addition to the ASC list.

In addition to the procedures considered by the APC Panel for removal from the inpatient list, Table 6 in the proposed rule includes other procedures that we proposed to remove from the inpatient list for payment under the OPPS for 2003. We applied the criteria discussed above in order to be consistent with the ASC list of approved procedures and with utilization data that indicate the procedures are being performed on an outpatient basis. We solicited comments on whether the procedures listed in Table 6 of the proposed rule should be paid under the OPPS. We also solicited comments on the APC assignment that we proposed for these procedures in the event we determine in the final rule, based on comments, that these procedures would be payable under the OPPS in 2003. We asked that commenters recommending reclassification of a procedure to an APC include evidence (preferably from peer-reviewed medical literature) that the procedure is being performed on an outpatient basis in a safe and appropriate manner.

Following our review of the comments, we either assigned a CPT code for a service formerly on the inpatient list to an APC for payment under the OPPS or, if the comments did not provide sufficient information and data to enable us to make a decision, we chose to keep the service on the inpatient list for 2003 and to present the comments to the APC Panel at its 2003 meeting. Table 6 identifies codes that were on the inpatient list in 2002 but are not on the inpatient list in 2003 and which, therefore, will be payable under the OPPS on and after January 1, 2003.

We received numerous comments on this proposal, which we summarize below.

Comment: In addition to the APC Advisory Panel, numerous hospital associations, hospitals, and other organizations recommended that we eliminate the inpatient list. They asserted that the inpatient list interferes with the practice of medicine and is unnecessarily intrusive. Most of these commenters argued that it is the physician, not the hospital, who determines what procedures should be performed and whether a patient's condition warrants an inpatient admission. Numerous commenters asserted that if CMS insists on retaining the inpatient list, then the same payment rules should apply to physicians as well as to hospitals. These commenters argued that if CMS believes Medicare beneficiaries are at risk for safety and quality issues, then Medicare should not pay for the professional services of the physician who performs a procedure on the inpatient list when payment for the hospital services is denied. In addition, several commenters noted that because the physician receives payment when a procedure on the inpatient list is performed on an outpatient basis, there is no incentive for the physician to heed whether Medicare will pay the hospital for the procedure. A few commenters noted that the inpatient list sometimes conflicts with the policy of private payers, creating confusion among physicians, patients, and hospitals. One commenter recommended that it should be left to medical review to monitor site of service. Several commenters viewed the inpatient list as an attempt to punish hospitals for a decision over which they have no real control. One commenter objected to the inpatient list because it places an unfair financial burden on beneficiaries, who are liable for payment if a procedure on the inpatient list is performed in the outpatient setting, and because the beneficiary normally relies on the physician to determine where a procedure is to be performed.

Response: Since implementation of the OPPS in August 2000, we have engaged in an ongoing review of the procedures on the inpatient list. In the August 9, 2002 proposed rule (67 FR 52092), we proposed APC assignments for 41 procedures that have a current status indicator designation of ''C''. We continue to move procedures from the inpatient list to an APC for payment under the OPPS in response to comments and recommendations from hospitals, surgeons, professional societies, and hospital associations which demonstrate that a procedure on the inpatient list meets our criteria for determining that a procedure can be performed on an outpatient basis in a

safe and effective manner. In spite of the assertions made by commenters, we have received very few requests since publication of the November 30, 2001 final rule.

Hospitals or associations representing hospitals submitted the overwhelming majority of comments recommending elimination of the inpatient list. Their comments expressed considerable frustration resulting from apparent conflicts with physicians over which procedures Medicare will pay for under the OPPS. Although we understand the frustration that exists in the hospital community about the inpatient list, we believe that appropriate education of physicians and other hospital staff by CMS, hospitals, and organizations representing hospitals is the best way to minimize any existing confusion. We are prepared to remove procedures from the inpatient list as part of the quarterly OPPS updates. If a physician believes that a procedure should be payable under the OPPS, we urge the hospital and physician to provide operative reports about specific procedures on the inpatient list are being performed on Medicare beneficiaries who are outpatients. In the meantime, we are reviewing with CMS provider education staff ways that we can support carrier and fiscal intermediary efforts to clarify the reasons for the OPPS inpatient list and its billing and payment implications. Also, in section X.C. of this preamble, we explain how hospitals can receive payment under certain conditions for procedures on the inpatient list that are performed on an emergency basis when the status of a patient is that of an outpatient.

Comment: We received a number of comments regarding the criteria that we 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, including the two new criteria that we proposed in the August 2002 proposed rule to add to the current criteria. One commenter asked what we meant by ''numerous'' hospitals. Several commenters commended CMS for recognizing that surgical procedures payable in the ambulatory surgical center (ASC) setting should also be payable in an outpatient hospital setting and for removing a number of codes from the inpatient list that are currently payable in an ASC. Several commenters urged CMS to closely monitor and coordinate the OPPS inpatient list and the ASC list for consistency and to ensure that changes in medical practice are reflected within both lists as expeditiously as possible. Commenters expressed concern that more than 60 CPT codes remain on the inpatient list in Addendum E even though they are currently on the approved ASC list and urged CMS to reconcile the disparity between the two lists.

Response: The criterion that a procedure is being performed in ''numerous'' hospitals on outpatients means that the procedure is being performed nationally in hospitals other than a few large teaching hospitals that specialize in innovative surgery. We intend to continue monitoring for consistency the procedures that Medicare pays for in a hospital outpatient setting with those that are payable in an ASC as we prepare a final rule to update the ASC list based on the additions and deletions that we proposed in the June 12, 1998 **Federal Register** (63 FR 32290).

Comment: One commenter recommended that CMS remove from the inpatient list those procedures that routinely show a one-day inpatient stay.

Response: We believe this recommendation has merit and we will endeavor to conduct a study to explore the issue in preparation for the 2004 OPPS update.

Comment: One commenter stated that CMS should have a formal process to solicit and act on suggestions to remove procedures where community medical standards and practice can demonstrate the safety and efficacy of performing the procedure in an outpatient setting. Another commenter stated that physician comments, outcome data, post-procedure care data, and medical literature would be better criteria for determining which procedures are outpatient.

Response: As we stated above, anyone interested in having a particular code or group of codes on the inpatient list reviewed for payment under the OPPS need only submit a request to the Director, Division of Outpatient Care, Centers for Medicare & Medicaid Services, Mailstop C4–05–17, 7500 Security Boulevard, Baltimore, MD 21244–1850. The request should include supporting information and data to demonstrate that the code meets the five criteria discussed above. We ask that evidence be submitted, including operative reports of actual cases and peer-reviewed medical literature, to demonstrate that the procedure is being performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals. We agree with the commenters suggestions, and encourage, in addition to medical literature, the submission of community medical standards and practice as well physician comments, outcome data, and post-procedure care data to reinforce the point.

When this information is received, it is thoroughly reviewed by our medical advisors within the context of the criteria we have established. Further information or clarification may be requested. If, following this review, we determine that there is sufficient evidence to confirm that the code can be safely and appropriately performed on an outpatient basis, we will assign the procedure to an APC and include it as a payable procedure in the next OPPS quarterly update. The change in payment status will be subject to public comment as part of the subsequent annual OPPS update.

Interested parties may also submit a request to change the payment status of a code on the inpatient list for consideration as an agenda item at the next meeting of the APC Advisory Panel.

Comment: One commenter expressed concern about the inpatient list becoming a ''self-fulfilling prophecy'' because hospitals cannot be paid for procedures on the list, therefore no data become available to show that the procedure is safely done on an outpatient basis.

Response: Information may be available on non-Medicare patients receiving a procedure on the list. Further, this is not the sole criterion upon which a change is based, as we note above.

Comment: One commenter recommended that CMS establish a transitional methodology for estimating appropriate hospital costs for CPT codes on the inpatient list that are proposed for payment under the OPPS. The commenter expressed particular concern about payment for CPT codes 92986, 92987, and 92990.

Response: The APC assignments for the CPT codes in Table 6 of the August 2002 proposed rule (67 FR 52115) for which we propose to make payment under the OPPS take into account the expectation that the simplest procedure described by the codes, and therefore, relatively, the least resource intensive, would be performed on an outpatient basis. Also, we identify APCs that consist of procedures that are similar both in terms of clinical characteristics and in terms of resource consumption. Finally, we invited comments on the proposed APC assignment. Over time, claims data for the newly assigned codes will confirm either that the procedures belong in the designated APC or that they should be moved to different APC.

Comment: Two commenters supported our proposal to remove CPT

code 47001, Biopsy of liver, needle; when done for indicated purpose at time of other major procedure, from the inpatient list. Several commenters supported generally our proposal to pay under the OPPS for the procedures in Table 6 of the proposed rule, but did not comment on our proposed APC assignments. One commenter urged that CPT code 92986, Percutaneous balloon valvuloplasty; aortic valve, not be assigned to APC 0083, asserting that this procedure cannot be performed safely in an outpatient setting. We received no other comments opposing payment under the OPPS for the procedures listed in Table 6 of the August 9 proposed rule.

Response: We agree with the commenters and with the APC Panel's recommendations that CPT code 47001 be payable under the OPPS beginning in 2003. Because this is an add-on code, payment will be packaged with the payment for the surgical procedure with which it is billed.

We are making final our proposal to remove this code from the inpatient list, but we will consider presenting this concern to the APC Panel. In the absence of comments disagreeing with our proposal to pay under the OPPS for the 41 CPT codes listed in Table 6 of the August 2002 proposed rule (67 FR 52115), we are making these proposed changes final.

Comment: One commenter favored removing CPT 33967, insertion of intra-aortic balloon assist device, percutaneous, from the inpatient list, but did not submit any information to support this position.

Response: We discussed in the proposed rule our uncertainty, and that of the APC Advisory Panel, about whether or not this procedure should be removed from the inpatient list. We also indicated that we were having difficulty finding data to confirm that the procedure is being performed on Medicare beneficiaries in an outpatient setting. We asked for comments and clinical data and case reports that would support payment for CPT 33967 under the OPPS. No commenters submitted data in any form to support removing the procedure from the inpatient list. Therefore, we have decided not to remove CPT 33967 from the inpatient list in 2003.

Comment: One commenter recommended payment for CPT codes 22612, 22614, 33243, 49000, and 49062 under the OPPS.

Response: Our medical advisors reviewed these codes and have determined that CPT 22612, Arthrodesis, posterior or posterolateral technique, single level; lumbar (with or without lateral transverse technique), and CPT 22614, Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (list separately in addition to code for primary procedure), are safely and appropriately being performed on an outpatient basis. We are assigning these codes to APC 0208.

We did not propose to remove the other codes suggested by the commenter from the inpatient list, and the commenter submitted no evidence to support payment for these codes under the OPPS. Nor could we find any information to indicate that these codes meet the criteria for moving them off the inpatient list. Therefore, we will continue to designate these CPT codes with status indicator ''C'' in 2003.

- We are adopting two additional criteria to guide our determination of whether a procedure should be removed from the inpatient list:
- The procedure is being performed in numerous hospitals on an outpatient basis; or
- The procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or proposed by us for addition to the ASC list.
- We are adding CPT codes 22612 and 22614 to APC 0208 effective for services furnished on or after January 1, 2003.
- We are making final our proposal in the August 2002 rule to pay under the OPPS for the CPT codes listed in Table 5, below.

TABLE 5.—PROCEDURES ON THE 2002 INPATIENT LIST WHICH ARE PAYABLE UNDER THE OPPS IN CY 2003

CPT Code	Status Indicator	APC	Description
21390	T	0256	OPEN TREATMENT OF ORBITAL FLOOR BLOWOUT FRACTURE; PERIORBITAL APPROACH, WITH ALLOPLASTIC OR OTHER IMPLANT.
22100	T	0208	PARTIAL EXCISION OF POSTERIOR VERTEBRAL COMPONENT (EG, SPINOUS PROCESS, LAMINA OR FACET) FOR INTRINSIC BONY LESION, SINGLE VERTEBRAL SEGMENT; CERVICAL.
22101	T	0208	PARTIAL EXCISION OF POSTERIOR VERTEBRAL COMPONENT (EG, SPINOUS PROCESS, LAMINA OR FACET) FOR INTRINSIC BONY LESION, SINGLE VERTEBRAL SEGMENT; THORACIC.
22102	T	0208	PARTIAL EXCISION OF POSTERIOR VERTEBRAL COMPONENT (EG, SPINOUS PROCESS, LAMINA OR FACET) FOR INTRINSIC BONY LESION, SINGLE VERTEBRAL SEGMENT; LUMBAR.
22103	T	0208	PARTIAL EXCISION OF POSTERIOR VERTEBRAL COMPONENT (EG, SPINOUS PROCESS, LAMINA OR FACET) FOR INTRINSIC BONY LESION, SINGLE VERTEBRAL SEGMENT; EACH ADDITIONAL SEGMENT (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE).
22612	T	0208	ARTHRODESIS, POSTERIOR OR POSTEROLATERAL TECHNIQUE, SINGLE LEVEL; LUMBAR (WITH OR WITHOUT LATERAL) TRANSVERSE TECHNIQUE).
22614	T	0208	ARTHODESIS, POSTERIOR OR POSTEROLATERAL TECHNIQUE, SINGLE LEVEL; EACH, ADDITIONAL VERTEBRAL SEGMENT (LIST, SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE).
23035	T	0049	INCISION, BONE CORTEX (EG, OSTEOMYELITIS OR BONE ABSCESS), SHOULDER AREA.
23125	T	0051	CLAVICULECTOMY; TOTAL.
23195	T	0050	RESECTION, HUMERAL HEAD.
23395	T	0051	MUSCLE TRANSFER, ANY TYPE, SHOULDER OR UPPER ARM; SINGLE.
23397	T	0052	MUSCLE TRANSFER, ANY TYPE, SHOULDER OR UPPER ARM; MULTIPLE.
23400	T	0050	SCAPULOPEXY (EG, SPRENGELS DEFORMITY OR FOR PARALYSIS).
24150	T	0052	RADICAL RESECTION FOR TUMOR, SHAFT OR DISTAL HUMERUS;
24151	T	0052	RADICAL RESECTION FOR TUMOR, SHAFT OR DISTAL HUMERUS; WITH AUTOGRAFT (INCLUDES OBTAINING GRAFT).
24152	T	0052	RADICAL RESECTION FOR TUMOR, RADIAL HEAD OR NECK;
24153	T	0052	RADICAL RESECTION FOR TUMOR, RADIAL HEAD OR NECK; WITH AUTOGRAFT (INCLUDES OBTAINING GRAFT).
25170	T	0052	RADICAL RESECTION FOR TUMOR, RADIUS OR ULNA.

TABLE 5.—PROCEDURES ON THE 2002 INPATIENT LIST WHICH ARE PAYABLE UNDER THE OPPS IN CY 2003—Continued

CPT Code	Status Indicator	APC	Description
25390	T	0050	OSTEOPLASTY, RADIUS OR ULNA; SHORTENING.
25391	T	0051	OSTEOPLASTY, RADIUS OR ULNA; LENGTHENING WITH AUTOGRAFT.
25392	T	0050	OSTEOPLASTY, RADIUS AND ULNA; SHORTENING (EXCLUDING 64876).
25393	T	0051	OSTEOPLASTY, RADIUS AND ULNA; LENGTHENING WITH AUTOGRAFT.
25420	T	0051	REPAIR OF NONUNION OR MALUNION, RADIUS AND ULNA; WITH AUTOGRAFT (INCLUDES OBTAINING GRAFT).
27035	T	0052	DENERVATION, HIP JOINT, INTRAPELVIC OR EXTRAPELVIC INTRA-ARTICULAR BRANCHES OF SCIATIC, FEMORAL, OR OBTURATOR NERVES.
27216	T	0050	PERCUTANEOUS SKELETAL FIXATION OF POSTERIOR PELVIC RING FRACTURE AND/OR DISLOCATION (INCLUDES ILIUM, SACROILIAC JOINT AND/OR SACRUM).
27235	T	0050	PERCUTANEOUS SKELETAL FIXATION OF FEMORAL FRACTURE, PROXIMAL END, NECK, UNDISPLACED, MILDLY DISPLACED, OR IMPACTED FRACTURE.
31582	T	0256	LARYNGOPLASTY; FOR LARYNGEAL STENOSIS, WITH GRAFT OR CORE MOLD, INCLUDING TRACHEOTOMY.
31785	T	0254	EXCISION OF TRACHEAL TUMOR OR CARCINOMA; CERVICAL.
32201	T	0070	PNEUMONOSTOMY; WITH PERCUTANEOUS DRAINAGE OF ABSCESS OR CYST.
38700	T	0113	SUPRAHYOID LYMPHADENECTOMY.
42842	T	0254	RADICAL RESECTION OF TONSIL, TONSILLAR PILLARS, AND/OR RETROMOLAR TRIGONE; WITHOUT CLOSURE.
43030	T	0253	CRICOPHARYNGEAL MYOTOMY.
47490	T	0152	PERCUTANEOUS CHOLECYSTOSTOMY.
47001	N	.....	BIOPSY OF LIVER, NEEDLE; WHEN DONE FOR INDICATED PURPOSE AT TIME OF OTHER MAJOR PROCEDURE.
62351	T	0208	IMPLANTATION, REVISION OR REPOSITIONING OF TUNNELED INTRATHECAL OR EPIDURAL CATHETER, FOR LONG-TERM MEDICATION ADMINISTRATION VIA AN EXTERNAL PUMP OR IMPLANTABLE RESERVOIR/INFUSION PUMP; WITH LAMINECTOMY.
64820	T	0220	SYMPATHECTOMY; DIGITAL ARTERIES, EACH DIGIT.
69150	T	0252	RADICAL EXCISION EXTERNAL AUDITORY CANAL LESION; WITHOUT NECK DISSECTION.
69502	T	0254	MASTOIDECTOMY; COMPLETE.
92986	T	0083	PERCUTANEOUS BALLOON VALVULOPLASTY; AORTIC VALVE.
92987	T	0083	PERCUTANEOUS BALLOON VALVULOPLASTY; MITRAL VALVE.
92990	T	0083	PERCUTANEOUS BALLOON VALVULOPLASTY; PULMONARY VALVE.
92997	T	0081	PERCUTANEOUS TRANSLUMINAL PULMONARY ARTERY BALLOON ANGIOPLASTY; SINGLE VESSEL.
92998	T	0081	PERCUTANEOUS TRANSLUMINAL PULMONARY ARTERY BALLOON ANGIOPLASTY; EACH ADDITIONAL VESSEL (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE).

C. Partial Hospitalization

Payment Methodology

As we discussed in the proposed rule, partial hospitalization is an intensive outpatient program of psychiatric services provided to patients in the place of inpatient 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). In the August 1, 2000 final rule (65 FR 18452), we established a per diem payment methodology for the PHP APC based on hospital data. The current per diem payment amount is $212.27. This amount represents the hospital or CMHC overhead costs associated with the program.

In the August 9, 2002 OPPS proposed rule, we proposed to revise the PHP APC using 2001 claims data from hospitals and CMHCs and computed a median per diem using the same methodology as that used for all other APCs. As we explained in the August 9, 2002 proposed rule, we adjusted the CMHC costs to account for the difference between settled and as-filed cost reports. We proposed that the resulting per diem is $256.96, of which $51.39 is the beneficiary's coinsurance.

In addition, to facilitate proper billing and ensure comparable reporting of costs by hospitals and CMHCs, we proposed to revise § 410.43 (Partial hospitalization services: Conditions and exclusions) to add CSW services that meet the requirements of section 1861(hh)(2) of the Act to the list of professional services not considered to be PHP services. Such revision would mean that hospitals and CMHCs could bill the carrier for CSW services furnished to PHP patients.

Comment: One commenter indicated that the proposed methodology for ratesetting is appropriate.

Response: As we indicated in the April 7, 2000 OPPS final rule, payment to providers under OPPS represents the facility costs, that is, overhead, support staff, equipment, and supplies. The physician and nonphysician practitioner services excluded from the definition of PHP services are those professional services paid through the physician fee schedule. The facility continues to incur the overhead costs associated with provision of the professional service, for example, room, heat, lights, mental health technicians, and nurses. The OPPS is intended to pay providers for the resource costs associated with their outpatient programs, including outpatient psychiatric programs and PHPs.

As part of our analysis of current billing instructions for PHP, we discovered that Addendum B of the November 30, 2001, CY 2002 OPPS final rule does not clearly identify all the HCPCS codes that may be billed for PHP patients. We plan to revise this addendum in the 2004 update so that all PHP services are identified. However, in order to avoid billing errors, we are providing the following list of the current HCPCS codes for PHPs:

Revenue codes	Description	HCPCS codes
43X	Occupational Therapy	G0129.
904	Activity Therapy	G0176.
910	Psychiatric General Services	90801, 90802, 90875, 90876, 90899.
914	Individual Psychotherapy	90816, 90817, 90818, 90819, 90821, 90822, 90823, 90824, 90826, 90827, 90828, 90829.
915	Group Therapy	90849, 90853, 90857.
916	Family Psychotherapy	90846, 90847, 90849.
918	Psychiatric Testing	96100, 96115, 96117.
942	Education/Training	G0177.

Comment: Two national behavioral health care organizations commented that the proposed PHP rate for CY 2003 more adequately represents the resources needed to provide PHP; however, they expressed concern that providers continue to have difficulty in receiving reimbursement for PHP services as a result of intermediary medical review (MR) of claims.

Response: As noted in the comment, we have issued a program memorandum to intermediaries regarding medical review of PHP claims. While we recognize that MR can have a financial impact on PHP claims, there is no direct relationship between MR and the level of reimbursement for individual claims.

III. Recalibration of APC Weights for 2003

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 for application in 2002. In the April 7, 2000 final rule (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group. Except for some reweighting due to APC changes, these relative weights continued to be in effect for 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, 2003, and before January 1, 2004, we proposed 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 proposed 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 2003, the most recent available claims data are more than 90 million final action claims for hospital outpatient department services furnished on or after April 1, 2001, and before March 31, 2002, and processed through July 2002. In the proposed rule, we proposed to base the 2003 OPPS on claims for services furnished January 1, 2001 through December 31, 2001. However, after issuance of the proposed rule we determined that coding and charges for the period of April 1, 2001 thru March 31, 2002 would be a better base for recalculation of weights.

We believe that using claims data from this period is consistent with section 1833(t)(9)(A) of the Act, which directs us to take into account ''new cost data'' in our annual review and adjustment of components of the OPPS. This is also consistent with our proposal in the August 9, 2002 proposed rule (67 FR 52108) to use the most recent available claims data to set the weights. We had several reasons for using claims from this period: claims from this period provide the most recent charge data available to us. Since we did not implement the 2002 OPPS until April 1, 2002, we can use the claims for the period from January 1, 2002, through and including March 31, 2002, together with claims data from the period of April 1, 2001 to December 31, 2001 to set weights. Using claims data for services furnished during this period of time also provides the most reliable charge data for devices and services that use medical devices because the device category codes were in effect for the entire period. Hence, we believe that claims from this period are the most reliable basis for setting relative weights for CY 2003 OPPS.

Many of the claims from hospitals were for services that are not paid under OPPS (such as clinical laboratory tests). We matched the claims that are paid under 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. Treatment of ''Multiple Procedure'' Claims

In the August 9, 2002 proposed rule, we discussed in detail the circumstances in which we had difficulty with using the data from claims that had multiple procedures (67 FR 52108). We solicited public comment on the methods we considered for apportioning the total charges to individual HCPCS codes as described above. These possible methods included: dividing the total charges in a revenue center, or for a packaged HCPCS code, by the number of payable HCPCS codes for the multiple procedures on the claim; apportioning the charges among the codes based on physician work relative value units (RVUs); apportioning the charges among the codes based on physician nonfacility practice expense RVUs; or requiring the hospital to apportion all charges currently shown in revenue centers to the HCPCS codes billed so that we could use all multiple services claims in the calculation of relative weights. We also invited suggestions of other alternative means of apportioning the total costs on multiple procedure claims to the HCPCS codes for the procedures so that we can use more data from multiple procedure claims in the 2004 update of the OPPS.

We also solicited information on existing studies that would provide comparative hospital outpatient resource inputs by HCPCS code. In addition, we welcomed suggestions for studies that we might undertake either to determine the relative value of OPD resources by HCPCS code or to provide a valid means of apportioning the charges among HCPCS codes when multiple surgical procedures are billed on the same claim with a single total charge for all services.

Finally, we solicited information regarding the extent to which efficiencies are realized when multiple services are furnished during the same visit or operative session.

The discussion of recalibration of relative weights in section III.B of this final rule summarizes the process that we used to determine the claims that could be used to set the weights.

Comments and our responses are summarized below:

Low Numbers of Services Used To Set Weights and Failure To Use Multiple Procedure Claims

Comment: Many commenters indicated that we used very few of the claims that were submitted for a particular service and that using so few claims resulted in lower weights than would have occurred if we had used all claims. Some commenters indicated that by using only single procedure claims and data from multiple procedure claims that met the criteria we set (see section III.A.I. of this final rule), we significantly reduced the validity of the cost data. Some commenters stated that by using median costs for procedures that can only be done as an add-on to other procedures, we had based the payment for the add-on procedure on data which, by definition, were faulty. Some commenters suggested that we needed to develop an allocation strategy that would enable us to use all multiple procedure claims, either based on a study of relative resource allocation or an arbitrary allocation that could be refined over the years. Some commenters asked that we reconsider our data trimming strategy to examine each claim that is eliminated by trimming for validity and to determine if it should be used. They asked that any claim that represents new technology be returned to the data set and used, notwithstanding its aberrancy.

Response: For 2003, we made great strides by increasing the number of claims used to set the OPPS weights from 39.9 million (66 FR 59885) for the 2002 OPPS to 62.2 million for the 2003 OPPS. We intend to review other means of using data from multiple claims for 2004. We recognize that it would be preferable to use data from all claims, including those with multiple procedures, in development of the weights, as long as we can ensure that the data recovered from those claims are valid. We were not able to develop and test a strategy for allocating undifferentiated charges to multiple HCPCS codes on a claim for the 2003 final rule. Therefore, in some cases, we continued to use data from small numbers of claims because many claims did not meet the tests for inclusion in the data set. As discussed in section II, the APC Panel recommended that we continue to rely on data from single procedure claims until we were able to validly allocate charges to multiple procedures, even in establishing payments for add-on codes. In addition, as requested by some commenters, we excluded claims for procedures that could not be performed without a device when the claim did not contain the device. This gave us a more valid base of claims on which to set the weight for that service but reduced the number of claims used for these APCs. It became clear from this activity that basing the weights on more claims does not necessarily result in more valid data because in the cases of these APCs, deleting claims from the set was necessary to arrive at a more valid relative weight.

With regard to the trimming methodology, it is a routine and accepted statistical practice that is well established in inpatient PPS data examination and has served well in the past to eliminate anomalies that could further skew the data. We will consider whether it is useful and to what extent it is practical to examine all trimmed claims to determine if they represent the first claims for a new technology and should remain in the body of claims.

Recommendations for Including More Multiple Procedure Claims

Comment: We received a number of comments that contained ideas for allocating charges to multiple procedures where they exist on the claim. Some commenters recommended that we allocate the charges to HCPCS codes in proportion to the relative weight of the HCPCS codes or the relative charges for the HCPCS codes. Some commenters suggested that we survey hospitals with regard to the most common combinations of procedures that appear on claims to determine which services and, therefore, which charges go with which HCPCS code. Some commenters suggested that we research the relative resources for each HCPCS code individually and then create an algorithm by which we would allocate charges to HCPCS codes on multiple procedure claims. One commenter provided a study that addressed the efficiency of resource usage when multiple procedures are performed on the same day that the commenter recommended could be useful in allocating charges for the second and subsequent procedures on a claim. One commenter also suggested that we ensure that the claim assesses services on the same date of service, since in many cases, the claim can have services that are spread over a period of time and, therefore, are not really multiple procedures provided at the same time. Several commenters submitted detailed descriptions of ways by which we could allocate charges to HCPCS codes. Many hospitals objected to any requirement that hospitals do the allocation of all charges to HCPCS codes to show the charges that go with each HCPCS code; they noted that doing so would require massive accounting and cost report changes and thus impose a burden and cost on hospitals, which would exist for no purpose other than to improve the Medicare OPPS claims data.

Response: We expect to explore a number of strategies for allocating charges to HCPCS codes on multiple procedure claims for the development of the 2004 OPPS and beyond.

Impact on Data of a Visit and Drug Administration the Same Day

Comment: Several commenters applauded our attempt to include some multiple procedure claims in the calculation of OPPS payment rates. They were, however, concerned whether some properly coded claims, which included both an administration code and a J code or claims that included an evaluation and management visit in addition to an administration code and a J code, were eliminated as multiple procedure claims.

Response: Where an evaluation and management visit and an administration code and J code were billed on the same claim, they would have been considered to be a multiple procedure claim and would not be used because there would be no way of knowing how to allocate the charges in revenue centers to the visit versus the administration code. As we explained in detail in the August 9, 2002 proposed rule, there would be no way to know to what extent charges in revenue centers, such as sterile supplies, were associated with the visit versus the administration code. We are concerned about this problem and are exploring ways to do an allocation of charges that would enable us to use all multiple procedure claims. However, we were not able to do it for this final rule.

2. Calendar Year 2002 Charge Data for Transitional Pass-Through Device Categories

In the August 9, 2002 proposed rule, we discussed our concerns with the claims data for the devices losing eligible for transitional pass-through status in CY 2003 (67 FR 52110). We had been advised that during the period in which the 2001 OPPS was in effect, hospitals may not have billed properly for devices eligible for transitional pass-through payments. We acknowledged in the 2002 proposed rule that changes in billing format and systems for implementation of the OPPS may have compounded the problems of billing using the device-specific codes during the first 9 months of the OPPS. We had been informed that these problems were

further compounded by the creation and requirement to use category codes on and after April 1, 2001. In general, we had been advised that hospitals may have been underpaid for transitional pass-through devices (because they did not bill separately for them and, therefore, did not get the pass-through payment) and that our data will not correctly show the charges associated with the devices (because the devices were not coded with device-category codes on the claim).

We proposed to package payment for devices into payment for the procedure in which they were furnished because doing so is consistent with the concept of a prospective payment system and because we believed that it would give us the best data on which to pay devices once they ceased to be paid at cost via the pass-through methodology. We thought that by packaging the cost of the devices into the cost of the procedure with which they were used, we would capture the charges for the devices whether billed in revenue centers or with the HCPCS code for the device.

Our subsequent review of the data for the period of April 1, 2001, through March 31, 2002, indicated that there was a notable absence of hospital billing for devices category codes, even when the procedure billed could not be done without a pass-through device. We calculated the median costs for the APCs containing procedures that we believed required use of devices (including both claims with and claims without device C codes on the claim) and compared them to the median costs for the procedures from only claims that were billed with devices. We found that the median costs on claims billed with devices were more consistent with the median costs that we would expect to see for these APCs. Hence, for these APCs, we used the median costs calculated from claims that reported a device C code in place of the median costs calculated from all claims (claims billed both with devices and without device C codes). We did not eliminate claims that did not contain a device C code where HCPCS codes within an APC indicated that the procedure did not require a pass-through device. In such cases, HCPCS codes were, appropriately, rarely reported with C codes. The APCs for which we used the medians from claims with device C codes billed are listed in Table 6. This methodology resulted in higher median costs and, therefore, higher weights for these APCs than would have occurred had we included claims that did not contain coding for a device. The medians we used for all APCs are contained in Addendum C, which is on our Web site at *http://www.cms.hhs.gov.*

TABLE 6.—APC RATES WHICH ARE SET BASED ONLY ON CLAIMS THAT CONTAINED CODES FOR DEVICES

APC	Description
0032	Insertion of Central Venous/Arterial Catheter.
0048	Arthroplasty with Prosthesis.
0080	Diagnostic Cardiac Catheterization.
0081	Non-Coronary Angioplasty or Atherectomy.
0082	Coronary Atherectomy.
0083	Coronary Angioplasty and Percutaneous Valvuloplasty.
0085	Level II Electrophysiologic Evaluation.
0086	Ablate Heart Dysrhythm Focus.
0087	Cardiac Electrophysiologic Recording/Mapping.
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes.
0655	Insertion/Replacement of Permanent Dual Chamber Pacemaker.
0090	Insertion/Replacement of Pacemaker Pulse Generator.
0680	Insertion of Patient Activated Event Recorders.
0653	Vascular Reconstruction/Fistula Repair with Device.
0104	Transcatheter Placement of Intracoronary Stents.
0106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes.
0107	Insertion of Cardioverter-Defibrillator.
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads.
0115	Cannula/Access Device Procedures.
0119	Implantation of Devices.
0122	Level II Tube changes and Repositioning.
0652	Insertion of Intraperitoneal Catheters.
0167	Level III Urethral Procedures.
0179	Urinary Incontinence Procedures.
0182	Insertion of Penile Prosthesis.
0202	Level VIII Female Reproductive Proc.
0222	Implantation of Neurological Device.
0225	Implantation of Neurostimulator Electrodes.
0226	Implantation of Drug Infusion Reservoir.
0227	Implantation of Drug Infusion Device.
0229	Transcatherter Placement of Intravascular Shunts.
0259	Level VI ENT Procedures.
0670	Intravenous and Intracardiac Ultrasound.
0680	Insertion of Patient Activated Event Recorders.
0681	Knee Arthroplasty.
0693A	Breast Reconstruction with Prosthesis.

Application of Cost-to-Charge Ratio to Charges Not Resulting in Costs

Comment: Many commenters stated that the application of a departmental cost-to-charge ratio to the high cost of devices would not result in the true cost of the device because hospitals would have to mark up the cost by 300 percent or more for that to be the result.

Response: See the discussion of the comments on cost to charge ratios and charge compression in section III.B of this final rule.

Absence of Devices on Claims

Comment: Many commenters indicated that hospitals did not bill for the devices that were paid under the pass-through mechanism in 2001, and therefore the median costs for the APCs for which most of the cost is a device are grossly understated.

Response: As discussed previously, we believe the commenters have a point. For the APCs for which the service cannot be furnished without a pass-through device, we eliminated claims that were not billed with a device C code from the claims used to calculate the median cost for those APCs. By taking these steps as well as packaging the device cost billed with both revenue centers and device category codes, we believe our final rates for these procedures are more appropriate. The APCs for which we used only claims with devices are identified in Table 6 above.

B. Description of How Weights Were Calculated for CY 2003

As discussed previously in this section, we first selected claims for services provided from April 1, 2001 through March 31, 2002. The methodology we followed to calculate the final APC relative payment weights for CY 2003 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 ESRD).
- We eliminated 1.6 million 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 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 301 hospitals that we identified as having reported charges on their cost reports, which were not actual charges (for example, a uniform charge applied to all services).
- We calculated the geometric mean of the total operating CCRs of hospitals remaining in the CCR data. We removed from the CCR data 67 hospitals whose total operating CCR exceeded the geometric mean by more than 3 standard deviations.
- We excluded from our data approximately 3.6 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 approximately 92.9 million claims to CCRs for remaining hospitals.
- We separated the 92.9 million claims that we had matched with a cost report into the following three distinct groups:

(1) Single-procedure claims.

(2) Multiple-procedure claims.

(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), which could be grouped to an APC. Multiple-procedure claims include more than one HCPCS code that could be mapped to an APC. Dividing the claims in this manner yielded approximately 30.7 million single-procedure claims and 20.4 million multiple-procedure claims. Approximately 41.8 million claims without at least one covered OPPS service were set aside.

We converted 10.8 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 chest X-rays (HCPCS codes 71010 and/or 71020) and/or EKGs (HCPCS code 93005) on these claims. If only one procedure (other than HCPCS codes 71010, 71020, and 93005) 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 claim if the line item was billed as a single unit.

(4) If the claim had no packaged HCPCS codes on the claim but had packaged revenue centers for the procedure, we ignored the line item for chest X-rays and/or EKG codes (as identified above) and if only one HCPCS code remained, we treated the claim as a single procedure claim. We created an additional 31.5 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. 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.1 of this final rule, we did not use multiple-procedure claims that included 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 other multiple-procedure bills to recalibrate APC weights that minimizes the risk of improperly assigning charges to the wrong procedure or visit.
- 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 departmental CCR. 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 we used the hospital's overall cost-to-charge ratio 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 the service. We observed the packaging provisions set forth in the April 7, 2000 final rule with comment period that were in effect during 2001 (65 FR 18484). For instance, in calculating the cost of a surgical procedure, we included charges for the operating room; treatment rooms; recovery; observation; medical and surgical supplies; pharmacy; anesthesia; casts and splints; and donor tissue, bone, and organs. To determine medical visit costs, we included charges for items such as medical and surgical supplies, drugs, and observation in those instances where they are still packaged. Table 7 lists packaged services by revenue center that we proposed to use to calculate per-service

costs for outpatient services furnished in CY 2003.

TABLE 7.—PACKAGED SERVICES BY REVENUE CODE

Revenue code	Description
	SURGERY
250	PHARMACY.
251	GENERIC.
252	NONGENERIC.
257	NONPRESCRIPTION DRUGS.
258	IV SOLUTIONS.
259	OTHER PHARMACY.
260	IV THERAPY, GENERAL CLASS.
262	IV THERAPY/PHARMACY SERVICES.
263	IV THERAPY/DRUG 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.
379	OTHER ANESTHESIA.
390	BLOOD STORAGE AND PROCESSING.
399	OTHER BLOOD STORAGE AND PROCESSING.
560	MEDICAL SOCIAL SERVICES.
569	OTHER MEDICAL SOCIAL SERVICES.
624	INVESTIGATIONAL DEVICE (IDE).
630	DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS.
631	SINGLE SOURCE.
632	MULTIPLE.
633	RESTRICTIVE PRESCRIPTION.
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.
	MEDICAL VISIT
250	PHARMACY.
251	GENERIC.
252	NONGENERIC.
257	NONPRESCRIPTION DRUGS.
258	IV SOLUTIONS.
259	OTHER PHARMACY.
270	M&S SUPPLIES.
271	NONSTERILE SUPPLIES.
272	STERILE SUPPLIES.
279	OTHER M&S SUPPLIES.
560	MEDICAL SOCIAL SERVICES.
569	OTHER MEDICAL SOCIAL SERVICES.
630	DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS.
631	SINGLE SOURCE DRUG.
632	MULTIPLE SOURCE DRUG.
633	RESTRICTIVE PRESCRIPTION.
637	SELF-ADMINISTERED DRUG (INSULIN ADMIN. IN EMERGENCY DIABETIC COMA.
700	CAST ROOM.
709	OTHER CAST ROOM.
762	OBSERVATION ROOM
942	EDUCATION/TRAINING.

TABLE 7.—PACKAGED SERVICES BY REVENUE CODE—Continued

Revenue code	Description
	OTHER DIAGNOSTIC
254	PHARMACY INCIDENT TO OTHER DIAGNOSTIC.
280	ONCOLOGY.
289	OTHER ONCOLOGY.
372	ANESTHESIA INCIDENT TO OTHER DIAGNOSTIC.
560	MEDICAL SOCIAL SERVICES.
569	OTHER MEDICAL SOCIAL SERVICES.
622	SUPPLIES INCIDENT TO OTHER DIAGNOSTIC.
624	INVESTIGATIONAL DEVICE (IDE). .
710	RECOVERY ROOM.
719	OTHER RECOVERY ROOM.
762	OBSERVATION ROOM.
	RADIOLOGY
255	PHARMACY INCIDENT TO RADIOLOGY.
280	ONCOLOGY.
289	OTHER ONCOLOGY.
371	ANESTHESIA INCIDENT TO RADIOLOGY.
560	MEDICAL SOCIAL SERVICES.
569	OTHER MEDICAL SOCIAL SERVICES.
621	SUPPLIES INCIDENT TO RADIOLOGY.
624	INVESTIGATIONAL DEVICE (IDE).
710	RECOVERY ROOM.
719	OTHER RECOVERY ROOM.
762	OBSERVATION ROOM.
	ALL OTHER APC GROUPS
250	PHARMACY.
251	GENERIC.
252	NONGENERIC.
257	NONPRESCRIPTION DRUGS.
258	IV SOLUTIONS.
259	OTHER PHARMACY.
260	IV THERAPY, GENERAL CLASS.
262	IV THERAPY PHARMACY SERVICES.
263	IV THERAPY DRUG/SUPPLY/DELIVERY.
264	IV THERAPY SUPPLIES.
269	OTHER IV THERAPY.
270	M&S SUPPLIES.
271	NONSTERILE SUPPLIES.
272	STERILE SUPPLIES.
279	OTHER M&S SUPPLIES.
560	MEDICAL SOCIAL SERVICES.
569	OTHER MEDICAL SOCIAL SERVICES.
630	DRUGS REQUIRING SPECIFIC IDENTIFICATION, GENERAL CLASS.
631	SINGLE SOURCE DRUG.
632	MULTIPLE SOURCE DRUG.
633	RESTRICTIVE PRESCRIPTION.
762	OBSERVATION ROOM.
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 FY 2003 hospital inpatient prospective payment system (IPPS) wage index published in the **Federal Register** on August 1, 2002 (67 FR 49982). 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 the proposed APC changes described in section II.A of this final rule.

• We calculated the median cost for each APC by using the claims for services included in the APC. In the case of APCs for which we eliminated the claims that did not contain device

C codes, we used only the claims that contained device codes to set the median cost for the APC. See section III.A.2 of this final rule for a complete discussion of why we used the device code medians for these codes (which are identified in Table 6).

• Using these 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. This approach is consistent with that used in developing RVUs for the Medicare physician fee schedule. 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 the 2001 through 2002 data, the median cost for APC 0601 is $57.56.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes and wage index changes be made in a manner that ensures that aggregate payments under the OPPS for 2003 are neither greater than nor less than, the aggregate payments that would have been made without the changes. To comply with this requirement concerning the APC changes, we compared aggregate payments using the CY 2002 relative weights to aggregate payments using the CY 2003 final weights. Based on this comparison, in this final rule, we are making an adjustment of .969 to the weights. The final weights for CY 2003, which incorporate the recalibration adjustments explained in this section, are listed in Addendum A and Addendum B of this final rule with comment period. The final weights are rounded to 4 decimals for greater precision.

We received many comments on the issues related to calculation of the OPPS payment weights, which we summarize and address below:

Changes in Payment Rates from 2002 to 2003

Comment: We received many comments expressing concern with the amount of decreases in payments for many services, in particular those that will include drugs and devices that will cease to be eligible for pass-through payment in 2003. Many commenters said that the costs for drugs and devices derived from claims data, on which we based weights for these APCs, were considerably below the acquisition price hospitals pay for the drugs and devices. Many commenters said that the proposed payments would result in hospitals ceasing to provide services that require expensive devices and drugs because they could no longer afford to furnish them under the proposed rates.

Response: We are concerned that our payments not compromise access of Medicare beneficiaries to high quality services involving new technologies. Accordingly, we have adopted a number of changes in our estimating procedures, as described in more detail below and elsewhere in this final rule, designed to better ensure that the payment rates we establish in this rule are as accurate and reasonable as possible.

Comment: Many commenters, in particular hospital organizations, supported the significant increases in payments for primary care and preventive services that were proposed. They strongly stated that we should rely only on Medicare claims data to ensure that these services would not be reduced in payment by increases to payments for device and drug related services, as happened in 2002 when external price data were used in the absence of Medicare claims data. They noted that the services that received increases in payments using 2001 claims data are furnished by all hospitals and that rural hospitals and small urban hospitals in particular are heavily dependent on adequate payment for these services to be able to continue to offer services to Medicare patients in their communities.

Response: We also are concerned that our payments not compromise access of Medicare beneficiaries to high quality services that may not involve new technologies; these services in fact represent the bulk of services in all hospitals. Accordingly, we have been mindful that increases in the payment on some services will result in decreases in others.

Comment: Many commenters shared with us data from various sources outside our claims data (for example, manufacturers' prices, prices reported by group purchasing organizations, and amounts from invoices as proof of acquisition price). Many of these commenters suggested we use these data as a substitute for or supplement to claims data for particular APCs or where particular drugs or devices are used.

Response: We appreciate the data that these commenters provided to us. We carefully reviewed all the data that were furnished to us and used the data to guide us in analysis of claims data and in making decisions regarding how to generate the final payment weights.

We note that the OPPS is not designed to pay hospitals their full accounting costs for delivery of particular services. The system was set up to be budget neutral to the prior system, which, under several provisions of the statute, paid approximately 82 percent of reported hospital outpatient department costs as shown on the cost reports. Payment rates for individual services are set, in essence, to reflect relative resource use within a payment system that pays at what was a discount of approximately 18 percent. Thus, for us to make changes to ensure that a particular service receives what observers believe is its ''full'' cost is difficult, partly because determination of ''full'' cost for a particular service is an uncertain exercise and partly because such a service could only be paid ''full'' cost at the expense of all other services, which in principle would be paid at an even greater discount than that already implied by the operation of the system. Accordingly, while we have used data from external sources to evaluate the reasonableness of our payment rates and to guide us in choice of methods that would achieve results as reasonable as possible, we have not directly substituted such data into our estimates.

Comment: Many commenters suggested that we use only claims on which pass-through devices had been coded to set medians for APCs containing procedures that required devices to be furnished.

Response: We agree that this suggestion presents a useful way to edit our data, and adopted it in calculating the rates presented in this rule. We calculated medians from our most current set of claims data using all claims, (that is, using claims with no device C code, and using claims with device C code) and compared the medians. We found that, in many APCs because the procedures require use of a pass-through device, the medians that resulted from using any claims on which device C codes were billed were more similar to the device and procedure costs provided by external data than were the medians calculated using all claims. For these APCs, shown in Table 6, we used the median calculated using only claims on which a device had been coded.

Comment: Many of the commenters asked that we adjust the weights so that no service, or at least no service for which a commenter had objected to a decrease, would receive a decrease in payment of more than 10 percent from 2002 to 2003.

Response: We agree that the substantial fall in payment rates for some APCs suggests the need for some approach to moderate the changes.

Many of these decreases appear to be linked to one or more of the following:

- Changes in the payment methodology for those drugs and devices that will no longer be eligible for pass-through payments,
- Miscoding,
- Restructuring of APCs (in which movement of a single code from one APC to another may change the median cost of both APCs), or
- Use of data from the period following implementation of the OPPS.

In the interest of using a method that could be employed simply and that could ensure that all APCs were treated similarly regardless of whether interested parties had identified them as sources of concern, we adopted a method that we applied to all APCs except new technology APCs, and APCs for drugs and devices that will receive pass-through payments in 2003.

We considered a number of different ways of moderating the reductions in payment that would have occurred under the August 9, 2002 proposed rule. We considered options that would have limited both significant increases and significant decreases in some fashion. However, we rejected these options because they would have reduced payments for those services that would otherwise have significant increases. Inspection of APCs that would have significant increases suggested that many of these increases were reasonable, and we did not want to reduce them more than necessary.

We considered options that would have created a fixed corridor that would have limited any reduction to some fixed value, such as 10 or 15 percent, as suggested by some commenters. However, we rejected this option, because it would have reduced the role of the claims data to a minimum, even though these data do reflect hospital charging behavior and are likely to have some degree of accuracy. In addition, setting an absolute floor on reductions would have shifted significant resources away from all other APCs.

We considered targeting those APCs that would experience a reduction in median costs beyond a threshold and limiting the reduction in median costs to half of the difference between the threshold level and the total reduction. Because of budget neutrality constraints, the costs of this approach must be met by reductions in other services. We concluded that setting a threshold at a 15 percent reduction and decreasing the reduction in median costs by half of the difference between the total proposed reduction and the threshold provided an appropriate balance, reflecting our assessment of the relative quality of claims data, other information from commenters, and the effects on services overall.

Thus, we adopt the following procedure. For any APC where the median cost would have fallen by 15 percent or more from between 2002 to 2003 from the values that would be otherwise applicable for 2003, after the data and method improvements noted above, we first decreased the reduction in median cost by one half of the difference between the value derived from the claims data and 15 percent. This methodology was applied to all APCs, not just those involving drugs or devices losing pass-through eligibility. We then assessed the results of this procedure with information from comments and concluded that several additional but more targeted steps were appropriate.

We examined further those APCs containing procedures involving devices where the device represented a very large portion of the overall costs. Noting that the overall reduction from cost discussed elsewhere in this section would mean that services where devices represented 80 percent or more of the total costs would leave virtually no margin to cover hospital costs in performing the procedure, we limited our attention to those APCs with device costs of 80 percent of more. We then calculated adjusted APC median costs for these APCs by determining the portion of the cost that was attributable to the procedure and summing it with a weighted average of the cost of the device. We determined the weighted average of the cost of the device by giving a weight of 3 to the median acquisition cost of the device as provided by external data and a weight of 1 to the median cost from our claims data. We then added the adjusted cost of the device to the unadjusted cost of the procedure to calculate the total cost of the procedure. Our dampening policy was then applied to the adjusted total cost of the procedure.

We believe that this process gave us credible adjusted medians for APCs 107, 108, 222 and 259. We gave external acquisition cost data a weight 3 times that of the adjusted claims median data because these APCs are disproportionately highly weighted with device costs and we recognize that our device data have weaknesses that would otherwise result in payments that are so low as to limit beneficiary access to these services.

We also examined further those APCs involving blood and blood products, and vaccines. Information from comments raised significant concerns about the payment reductions that would result, even after improvements in data and methods and the adjustments described above were applied, on blood and certain blood products (including antihemophilia factors). Considering the importance of these products to ongoing operation of hospitals, the short shelf life of many of them, other peculiarities of their distribution, and possible adverse effects on public health, we concluded that these products should be further protected from decreases. Accordingly, we limited the reduction in the median cost from 2002 to 2003 for these products to 11 percent, which resulted in limiting the reduction in payment from 2002 to 2003 to about 15 percent. We did this for the APCs listed in Table 8.

We also adopted specific changes relating to vaccines and certain orphan drugs, as described elsewhere in this final rule.

We created unscaled weights for all APCs by dividing the adjusted medians by the median cost for APC 601 (mid level visit). We then scaled the weights for budget neutrality. The budget neutrality scaler that we applied to the weights was .968969.

TABLE 8.—BLOOD AND BLOOD PRODUCTS WITH SPECIAL LIMITS

APC	Description
0949	Plasma, Pooled Multiple Donor, Solvent/Detergent T.
0950	Blood (Whole) For Transfusion.
0952	Cryoprecipitate.
0954	RBC leukocytes reduced.
0955	Plasma, Fresh Frozen.
0956	Plasma Protein Fraction.
0957	Platelet Concentrate.
0958	Platelet Rich Plasma.

TABLE 8.—BLOOD AND BLOOD PRODUCTS WITH SPECIAL LIMITS—Continued

APC	Description
0959	Red Blood Cells.
0960	Washed Red Blood Cells.
0966	Plasmaprotein fract,5%,250ml.
1009	Cryoprecip reduced plasma.
1010	Blood, L/R, CMV-neg.
1011	Platelets, HLA-m, L/R, unit.
1013	Platelet concentrate, L/R, unit.
1016	Blood, L/R, froz/deglycerol/washed.
1017	Platelets, aph/pher, L/R, CMV-neg, unit.
1018	Blood, L/R, irradiated.
1019	Platelets, aph/pher, L/R, irradiated, unit.
9500	Platelets, irradiated.
9501	Platelets, pheresis.
9502	Platelet pheresis irradiated.
9503	Fresh frozen plasma, ea unit.
9504	RBC deglycerolized.
9505	RBC irradiated.
9506	Granulocytes, pheresis.
0925	Factor viii per iu.
0926	Factor VIII (porcine) per iu.
0927	Factor viii recombinant per iu.
0928	Factor ix complex per iu.
0929	Anti-inhibitor per iu.
0931	Factor IX non-recombinant, per iu.
0932	Factor IX recombinant, per iu.
1409	Factor viia recombinant, per 1.2 mg.
1618	Vonwillebrandfactrcmplx, per iu

Comment: Many commenters, while indicating appreciation for our efforts to use data from multiple claims in determining relative weights as described in the August 9, 2002 proposed rule, believe that we have not done enough. Although we have significantly increased the number and proportion of claims that enter the calculation for relative weights, commenters asserted that, in particular, clinical areas, our mobility to draw on multiple claims distorts the relative weights assigned to services, because in normal circumstances certain services would always be performed with other particular services. If packaged services also appear on such claims, the claims would not be used in our current methodology, and relative weight calculations may not be as accurate as desired as a result. These commenters urged us to do more to include data from multiple claims.

Response: We appreciate the recognition of the methodological improvements that we have been able to accomplish this year. Although intend to continue the gains achieved for 2003, the development of appropriate methods is difficult. Further methodological development may be very detailed and involve clinical review of particular areas of services. We have been unable to develop any further methodological changes at present, so for 2003, we are adopting the same methods we proposed. We wish to develop further methods of allocation that will permit use of more multiple claims in the future, particularly in problem areas identified by commenters, and we hope to be able to make further progress in this area in time for the 2004 update.

Comment: Several commenters raised questions about our editing procedures relating to which claims were used in analysis. On one hand, some questioned whether our standard method of trimming claims with values over three standard deviations above the median was appropriate, or whether it might leave out reasonable claims involving newly disseminating, high cost technologies. Other commenters suggested that we edit the claims more restrictively, removing from analysis claims with values outside a clinically relevant range (of drug dosages, for instance).

Response: While we think the suggestions made by these commenters deserve further consideration, we have made no changes in developing the estimates for the final rule. Our procedure for trimming claims with values above three standard deviations, an exceedingly small proportion of claims, is a standard procedure we use in estimates for several payment systems. This procedure prevents undue influence on the estimates by claims that have a high probability of coding errors, and we have no particular indication that this procedure is inappropriately applied in this system. Establishing clinically relevant ranges would be difficult. The most obvious method would involve establishment of norms of particular services based on the judgment of clinicians, but these judgments might not be validated by actual experience in the field. We would have to develop this idea more thoroughly before adopting it. Accordingly, for 2003 we are using the trimming and editing procedures rules described in the August 9, 2002 proposed rule.

Comment: Several commenters noted that hospital coding appeared to improve over the course of 2001, based on quarter-by-quarter examination of claims data.

Response: We agree that hospital coding practices appear to have improved during the early months of the implementation of the OPPS. Because accurate coding now has definite implications for payment that it lacked in the past, this change was expected and comports with our experience in implementing other payment systems. To improve the quality of estimates for this final rule, we changed the reference period of the data used for the final rule by one quarter. The August 9, 2002 proposed rule was based on data from calendar year 2001; for the final rule, we dropped data from the first quarter of 2001 and added data from the first quarter of 2002. We were thus able to draw on data from a more recent period

while maintaining approximately the same number of claims for analysis. This change was possible in this instance because the implementation of the 2002 update on April 1, 2002 meant that the coding during the first quarter of calendar year 2002 was unchanged from the prior year. We believe that this change has improved the quality of our estimates.

Comment: Commenters asked a number of very detailed questions about our data and methods of calculation.

Response: Within a few weeks of the publication of this rule, we expect to invite interested parties to a meeting at our headquarters in Baltimore to discuss these and other questions regarding methods and estimates with our technical staff.

Use of Cost-to-Charge Ratios and Charge Compression

Comment: A number of commenters raised concerns about our use of cost-to-charge ratios in determining median costs of items and services. Of particular concern is the effect of our procedure on the costs we calculate for high-cost drugs and devices. These commenters asserted that hospitals markup their acquisition costs of drugs and devices by different percentages depending on the cost of the item. If so, application of cost-to-charge ratios that do not take this effect into account would result in a relative weight (and hence payment) for a high-cost item that was inappropriately low. Commenters asserted that differential mark-up behavior, sometimes referred to as ''charge compression,'' is common among hospitals, at least on purchased inputs such as implantable devices.

To illustrate, assume cost-to-charge ratios are about generally 50 percent. That would imply that an item that cost, for example, $100, would be marked up by 100 percent to $200. ($100/$200 = .5) If the hospital decided to mark up the cost of a high cost item by only 50 percent, the charge for an item that cost $1,000 would be $1,500, and the cost-to-charge ratio would be 67 percent. ($1,000/$1,500 = .67) On the other hand, the hospital might choose to mark up a low cost item by 150 percent: The charge for an item that cost $10 would be $25, and the cost-to-charge ratio would be 40 percent ($10/$25 = .4).

Commenters did not provide any useful empirical information on issues such as those above. One commenter presented results of a statistical analysis of the relation of average wholesale price (AWP) of some drugs to our proposed payments, but we do not know if average wholesale prices vary uniformly in proportion to the acquisition costs of hospitals and consequently do not find this analysis particularly informative.

Response: We calculate OPPS payment rates based on the charges made by the hospitals on OPD claims, reduced to costs by application of a cost-to-charge ratio that is either specific to each of the various departments of each hospital or, in cases where data are inadequate, to the individual hospital as a whole. Costs are not available on a service-specific basis, but are reported on each hospital's cost report by revenue center, which can in turn be grouped by department. Thus, the service-specific amount claimed is multiplied by the departmental cost-to-charge ratio to convert it into a measure of the cost on a service-specific basis. We then use these costs to adjust the relative weights for the various APCs as part of the annual update process.

In making this calculation, we are assuming that the ratio of cost to charges is constant across all services to which it is applied. This assumption has proved workable in the inpatient setting for almost 20 years. The calculations may not perfectly capture the costs identified for particular services, but as long as we use them in a set of relative calculations, any deviations should largely cancel out. However, if hospitals do not mark-up services in a uniform fashion within departments, the payment rates resulting from application of this assumption would be too low for some services (and too high for others), and the rates would create incentives for hospitals to avoid (or favor) particular services.

This postulated behavior of hospitals is not implausible, as they may attempt to avoid adverse reactions to high prices among consumers and to reduce coinsurance burden on high cost items used infrequently. However, the possibility of differential mark-up behavior is not well documented empirically. We do not know if differential mark-ups are common across many hospitals or across many services. Further, we do not know the size of any differential that may exist. Do hospitals apply differential mark-ups to all services or only to certain purchased inputs? Do they apply differential mark-ups only above some threshold (such as $1,000), or does the mark-up vary in some uniform fashion with the cost of the service?

In the face of the paucity of reliable empirical information on this issue, we find that we cannot move quickly to revise our current methodology. We are adopting our proposed methodology for calculating cost-to-charge ratios for 2003. We believe this issue merits further study, and we expect to address it further in the future.

Use of Means Rather Than Medians To Set Weights

Comment: Some commenters suggested that CMS use means rather than medians to set rates because means will result in higher values for device-related APCs than using medians. Some commenters noted that means are a better measure of central tendency because medians are so sensitive to the atypical distribution of new technology services within an APC. Some commenters recommended that if we use medians, we should revise the data set by deleting claims for services that require a device if the device was not billed.

Response: We will explore the possibility and potential impact of using means rather than medians for the 2004 OPPS. We lacked the resources and time to explore the impact of this change for the final rule with comment. However, since the purpose of these measures is to create relative payment weights, it does not necessarily follow that basing the relative weights of services on means will cause a change to the weights in a manner that would satisfy the commenter. We did, however, revise the data set by deleting claims for procedures that required a device if the device was not billed.

Collect at Least 3 Years' Data for Pass-Through Devices Before Setting Rates Based on Claims Data

Comment: Commenters recommended that we not use claims data to set weights for pass-through devices unless they have at least 3 years of claims data for the device. They argued that this was the minimum amount of time needed to allow stability in the hospitals' coding and charges for the items.

Response: We cannot ensure that we will wait for 3 years to pass before we will set payments based on data for new devices. The statute provides for no less than 2 years and no more than 3 years payment under pass-through for items that do not fit a previously existing device category. Hence, in most cases, items will not have received 3 years of transitional pass-through payment before they are priced based on costs. Moreover, many new devices do not receive pass-through status because they fit in a category that previously met the criteria and, once pass-through payment is no longer permitted for the category, these devices will be paid through payment for the procedure in which they are used from their first use.

In general, the statute requires us to use costs as the basis for the weights.

Claims data are the single national uniform basis of cost data for all OPD items and services. Other data sources are fragmented and are not national in scope, and may be biased in various ways. We believe that 2 years provides a sufficient time for hospitals to establish coding practices and to determine what charges to impose for items and services paid under the OPPS and that this will be even more true in the future as hospital coders and billers become more accustomed to HCPCS coding and the impact of charges on future payments.

Continue 2002 Weights for 2003 and Train Hospital Staff Coders and Billers Because Claims Data Are Flawed

Comment: Some commenters asserted that Medicare 2001 claims data are so badly flawed that the weights should be left untouched for 2003. They requested that we should initiate training of hospital staff billers and coders to ensure that future data accurately reflect the codes of the services furnished and that the charges accurately reflect the costs of drugs and devices.

Response: We have decided to revise the weights for 2003 based on the best available information. We believe that the adjustments and moderations we have made to the median costs for the services that would have been most adversely affected under the methodology used in the August 9, 2002 proposed rule have enabled us to establish a valid set of relative weights for the 2003 OPPS. This comports with the requirement of section 1833(t)(9)(A) of the Act that we review and revise the relative weights annually to take into account new cost data and other relevant information, and factors. Regarding training of hospital staff, we have greatly expanded our efforts to assist providers in complying with all Medicare rules, including creation of the Medlearn Web site, issuance of specialized articles and provider seminars. However, the fundamental responsibility for correct coding and billing for services lies with the hospitals who are paid under the OPPS system and who have every incentive to bill correctly to ensure that they are paid for all the services they furnish to Medicare beneficiaries.

Release of Crosswalk for Packaging Costs to Specific APCs

Comment: Some commenters asked that we release the crosswalk used to assign pass-through device costs to specific APCs. They indicated that without this crosswalk, they are unable to make specific comments and they urged the Congress to fund an additional activity to correct APCs they determine to be severely underfunded after they perform this analysis.

Response: There is no CMS-generated crosswalk that was used to assign pass-through device costs to APCs. We relied upon the coding of hospitals in their packaging of devices, drugs, and other items and services into the payment for the procedure in which they were used. We will make a public use file available that containing the claims data used to set the final payment weights. By examination of these data, interested parties can determine what was packaged into the medians for the APCs. While we recognize that the claims may contain errors, we believe that the probability of making errors in crosswalking services to procedures is reduced by accepting what providers bill as the items and services furnished with the procedure.

Impact of Medical Education on OPPS Payment Adequacy

Comment: Several commenters noted that payment under OPPS does not take into account the time and cost components associated with providing teaching services in teaching hospitals and thereby puts teaching hospitals at a disadvantage. Moreover, teaching hospitals are typically on the cutting edge of development and implementation of new innovations, technological and otherwise and would therefore be underpaid by the low payments proposed for APCs that use expensive devices. The commenters asked that Medicare provide an indirect medical education (IME) payment percentage add-on for all outpatient APCs similar to the IME factor used to adjust DRG payments for inpatient services.

Response: We have not developed an IME add-on for payments made under the OPPS because the statute does not provide for this adjustment, and we are not unconvinced that it would be appropriate in a budget-neutral system in which such changes would result in reduced payments to all other hospitals. Moreover, in the final rule, we have developed payment weights that we believe resolve many of the issues with payments for devices for which payment is packaged into the payment for the procedure in which the device is used. These and other payment changes should help ensure equitable payment for all hospitals as provided within the constraints of the statute.

Elimination of Payment for Cochlear Implants and Vagus Nerve Stimulators

Comments: A number of commenters objected to what they believed was a proposal to eliminate payment for cochlear implants and vagus nerve stimulators. Those who had the implant indicated that these devices had greatly improved their lives, or others who were expected to have the device implanted objected to what they believed was a proposal to no longer pay for them.

Response: We did not propose to cease payment for these devices under Medicare or to cease payment for services needed to implant them. We did propose payment amounts for 2003, and, in this final rule, we provide the payment rates that will determine payments under the OPPS in 2003. The establishment of payment amounts does not constitute a Medicare determination that these items and services are or are not covered in any particular case.

Underfunding of OPPS in General

Comment: Some commenters stated that OPPS was severely underfunded when it was established and it will never result in adequate payment of costs under its current budget neutrality requirements. They asked that we support their efforts to seek increased funding for outpatient services since hospital care is increasingly furnished in the outpatient setting and because continued absence of adequate funding will result in reduced access to services. Some commenters indicated that since the budget neutrality scaler is determined on the basis of estimates, we have considerable latitude to ensure that payments are as close to costs as possible, notwithstanding that the base was set at 82 percent of cost when the system was established.

Response: We do not believe that the OPPS system is severely underfunded, nor do we believe that the statute gives us flexibility in the determination of budget neutrality. Congress set the OPPS system to be budget neutral to the total payments under prior payment methods; those methods, as result of several statutory provisions dating back to FY 1990 and FY 1991, paid for hospital outpatient department services at approximately 82 percent of costs. We understand that observers at the time believed that hospitals had shifted accounting costs that might otherwise have been attributed to inpatient cost centers to the outpatient setting because the inpatient PPS limited hospital payment on the inpatient side while the outpatient side was not similarly constrained. Congress had thus reduced payments for outpatient department services below nominal costs, and the OPPS was set to be budget neutral relative to total payments under the prior system. Whether this situation

implies that hospital outpatient departments are underfunded under the OPPS is hard to judge.

With respect to budget neutrality, section 1833(t)(9)(B) of the Act makes clear that any adjustments to the OPPS made by the Secretary may not cause estimated expenditures to increase or decrease. We do not believe the statute provides us authority to depart from budget neutrality simply because it uses the word ''estimated.''

Data Issues Peculiar to Radiopharmaceuticals

Comment: Commenters stated various reasons why it would be inappropriate to use the 2001 claims data to calculate the median cost of radiopharmaceuticals. They claimed that additional costs unique to radiopharmaceuticals, such as overhead costs for nuclear pharmacies and safety/regulatory costs, were not reported in the 2001 claims. Also, they believe not all hospitals billed for their costs, particularly costs for overhead items, to the appropriate revenue codes. Therefore, they argue this misallocation of charges resulted in an underestimate of the cost-to-charge ratios that were used to set the payment rates. The low volume of claims for radiopharmaceuticals in the 2001 dataset may be attributed to the use of HCPCS A4641, which many hospitals used for radiopharmaceutical billing, instead of more specific coding. Also, they suggested that we did not receive reliable reporting data from the hospitals because of significant descriptor and payment rate changes in 2001. Thus, they recommended that we not implement the proposed changes until more accurate data on hospital costs could be collected.

Response: As discussed elsewhere in this section, we believe that we have satisfactorily resolved the data issues in the claims data for 2001 to enable us to create an appropriate set of relative weights for OPPS services for 2003. We find no justification for delaying the update of the 2003 OPPS. Moreover, we see nothing unique in the issues raised in the context of data for radiopharmaceuticals. As with other services, the costs in revenue centers and for A4641 were packaged into the procedure with which the items were billed. Similarly, we do not believe that the problem with multiple procedure claims is more of a problem for radiopharmaceuticals than for other services that are commonly provided in combinations. Lastly, there were significant descriptor and payment rate changes for all services paid under OPPS in 2001, and the extent of the changes for radiopharmaceuticals did not differ significantly from the extent of changes for other items and services.

Methodological Reasons That the Data for Drugs Are Flawed

Comment: Many commenters asserted that there are significant methodological problems in the 2001 claims data for drugs and biologicals, especially the high cost items. They said that the 2001 claims data do not reflect appropriate codes and charges for separately paid drugs and biologicals and that the proposed payment rate does not take into account additional pharmacy overhead costs. They indicated that when we process a claim, we reject the second and subsequent line if it is identical to a previously billed line as a duplicate claim and that, therefore, the subsequent lines are not included in the claims data. They maintained that the methodology of analyzing single line-items on drug claims is not consistent with how hospitals bill for particular drugs and biologicals. They stated that claims reported by hospitals for certain drugs and biologicals showed unit amounts that fell outside a therapeutic range and therefore should have been excluded from the body of claims used to set the rates. They said that many drugs and biologicals have a low HCPCS code dose that skews the computation of the relative weights, and thus the payment rates for these products.

Response: We recognize that not all hospitals billed properly for drugs and biologicals in 2001. However, since most payment for drugs and biologicals was made on a pass-through basis at 95 percent of AWP in 2001, hospitals had a significant incentive to bill properly and we believe that in most cases they billed properly for the services they furnished so as to receive payment for them. We recognize that if a claim was submitted in a manner that caused it to be rejected by duplicate claims edits, it would not appear in the data. However, we expect that in those cases, hospitals would submit an adjustment bill to secure payment for the full service and that the costs for the drugs or biologicals as shown in the adjustment bill would be reflected in the data. We also recognize that some claims reflect that the drugs were furnished in amounts that were outside of therapeutic ranges. However, we have no reason to believe that those claims do not represent what actually was furnished to the patient. Should a physician deviate from standard therapeutic ranges in particular a case, it is reasonable to expect the claim to reflect what was administered. With regard to the low dose of the HCPCS code, the payment is set based on the definition of the code and so to the extent that the drug or biological is correctly coded on the claim, the claims data would reflect the cost of the drug or biological.

Elimination of Data for Hospitals Without Actual Charges

Comment: Several commenters raised concerns regarding the elimination of about 3 million claims from 301 hospitals because their reported charges were not actual charges. The commenters requested the following information from us on the effect of eliminating these claims: Did the elimination of this information create more bias against higher cost drugs and biologicals? Were the claims from certain specialty hospitals?

Response: There is no way for us to determine what effect would have taken place if these hospitals had reported charges as other hospitals did. However, because we know that the reported charges for these hospitals are not actual charges, we know that the information provided by these hospitals is meaningless for the purpose of calculating payment rates under OPPS.

Impact of Rounding of Relative Weights for Drugs

Comment: Commenters stated that the rounding of relative weights down to only two decimal places causes a significant reduction in payment. For example, rounding a unit down to a relative weight of 0.01 from a greater amount (for example, 0.01433) can substantially decrease the payment amount of a therapeutic dose.

Response: We rounded relative weights to 4 decimal places in the final rule.

Comment: A commenter indicated that we included data from the 11 PPS-exempt cancer hospitals that should have been excluded from the rate-setting calculations.

Response: We disagree with the commenter's concern. According to 42 CFR 412.23(f), cancer hospitals that meet specific criteria are excluded from the inpatient PPS; however, these hospitals are not excluded from OPPS. Rather, under OPPS, cancer hospitals are held harmless. The hold harmless provision is set forth in our existing regulations at 42 CFR 419.70(d)(2). Therefore, we do not exclude claims for services furnished in these hospitals in our rate setting calculations.

Need for a Special Exceptions Process

Comment: Some commenters said that CMS should have a process by which hospitals should be able to submit special documentation to indicate that

unusual conditions exist and be paid an additional amount set by the contractor for the unusual conditions or costs that the hospital is incurring. They suggested this as a means of being assured of recouping costs where the APC payment would not otherwise reimbursement for full costs.

Response: We did not accept the comment because the OPPS already has an outlier system that provides for an additional payment when costs are incurred that meet the outlier criteria.

Claims Process

Comment: One commenter said that the implementation of OPPS was extremely daunting to providers because it was so different from prior billing and coding for these services and because CMS processes and rules changed so frequently. They indicated that software vendors often lagged behind CMS requirements and that errors in either provider billing or intermediary processing often required a hospital to detect a problem and resubmit claims. Moreover, the volume of claims can cause a small problem to become a large problem in very little time. They ask that CMS do whatever it can to simplify the processes they must undertake to achieve submission of a ''clean'' claim.

Response: We recognize that implementation of CMS was difficult for providers and we have tried to do all that we can to simplify billing and payment rules and to respond to problems as they arise. Most recently, the hospital open door forum calls have provided a means for hospitals to bring problems to the attention of the CMS staff as quickly as possible so that they can be resolved.

Reduced Quality of Care for Gamma Knife Services

Comment: A commenter said that reducing payment for hospital services for G0242 will force hospitals to reduce the hours of work for medical physicists in the hospital and will therefore decrease quality by increasing the opportunity for errors in the calculations that must be done before treatment.

Response: We believe that hospitals would not jeopardize themselves by decreasing the extent to which they ensure that errors are not made.

We are finalizing our rate methodology for PHP, including data from hospital outpatient and CMHC programs. The national unadjusted rate for CY 2003 will be $240.03, of which $48.17 is the beneficiary's national unadjusted coinsurance. Upon further review we have determined that we will not include the issue of separate billing for clinical social worker services provided to PHP patients in this final rule but will address it in future rulemaking.

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 biologicals.

For those drugs, biologicals, 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 could not be described as current, 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 are to 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. On March 22, 2001, we issued two Program Memoranda, Transmittals A–01–40 and A–01–41 that established the initial categories. We posted them on our Web site at *http://cms.hhs.gov.*

Transmittal A–01–41 includes a list of the initial device categories and a crosswalk of all the item-specific codes for individual devices that were approved for transitional pass-through payments as of January 21, 2001 to the initial category code by which the device is 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 biologicals are identified by status indicator ''G.'' Subsequently, we added two additional categories and made clarifications to some of the categories' long descriptors found in transmittal A–01–73. A current list of device category codes in effect as of July 1, 2002 can be found in Transmittal A–02–050, which was issued on June 17, 2002. This Program Memorandum can be accessed on our Web site at *http://cms.hhs.gov.* The list is also included in this preamble in Table 7.

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 are the subject of a separate interim final rule with comment period that we published in the **Federal Register** on November 2, 2001 (66 FR 55850). We respond to public comments on that interim final rule in this final rule with comment that implements the 2003 OPPS update.

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

The processes 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://cms.hhs.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) under the Paperwork Reduction Act (PRA). Notification of new drug, biological, or device category application processes are generally posted on the OPPS Web site at *http://cms.hhs.gov/Medicare/hopps/default.asp.*

As we indicated in the NPRM (67FR52130), Determining that a drug or biological is eligible for a pass-through payment or making a decision to pay a drug or biological on a separate APC basis (rather than packaging payment into payment for a procedure) does not represent a determination that the drug or biological is covered by the Medicare program.

CMS and its contractors make coverage determinations and the FDA makes premarket approval decisions under different statutory standards. Whereas the FDA must determine that a product is safe and effective as a condition of approval, CMS must determine that the product is reasonable and necessary as a condition of coverage under section 1862(a)(1)(A) of the Social Security Act. Under a premarket approval review, the FDA determines whether or not the product is safe and effective for its intended use that is

stated in its proposed labeling. Medicare evidence-based NCD reviews consider the medical benefit and clinical utility of an item or service in determining whether the item or service and its expenses are reasonable and necessary under the Medicare program. Unlike the FDA safety and effectiveness evaluation, CMS determines whether or not the product is clinically effective, that is, does the item or service improve net health outcomes in the Medicare population as compared to other covered technologies or procedures. CMS and its contractors do require that a drug or biological first be approved by the FDA, although not necessarily for the indication for which coverage is sought. CMS and its contractors also strongly consider the FDA's evaluation when making a coverage determination for a product and do not substitute their judgment for that of the FDA's regarding safety and effectiveness. Instead, we focus our review on the issues that are unique to Medicare's reasonable and necessary determination. (We note that approval of a product by the FDA as a drug or biological does not automatically assure that Medicare payment for the product will be as a drug or biological. The product must still be placed into the most appropriate Medicare benefit category before Medicare can make appropriate payments.)

In the case of an FDA-approved indication for drugs and biologicals, CMS and its contractors have generally considered that use to be reasonable and necessary, without performing a separate review, although Medicare has always retained the right to perform a separate evaluation. (See, for example, 54 FR 4302, 4306, January 30, 1989) (Proposed Rule-Coverage Criteria) (''Questions regarding coverage of drugs and biologicals are rarely referred to PHS since we have determined as a matter of national policy that drugs or biologicals approved for marketing by FDA are safe and effective when used for indications specified in their labeling.'') (emphasis added); Medicare Carriers Manual section 2049.4 (''Use of the drug or biological must be safe and effective *and otherwise reasonable and necessary*. Drugs or biologicals approved for marketing by the Food and Drug Administration are considered safe and effective for purposes of this requirement when used for indications specified on the labeling.'' (emphasis added). Under section 2049.4, our contractors ''*may* pay for the use of an FDA approved drug or biological, if: (1) It was injected on or after the date of the FDA's approval; (2) It is reasonable and necessary for the individual patient; and (3) All other applicable coverage requirements are met.'' (emphasis added).

CMS developed this approach, because, in the past, it was a more efficient mechanism for coverage and the impact of drugs and biologicals on the Medicare program was relatively small. Now, as a result of the increasing number of novel therapies on the market and the impact of new drugs and biologicals on the Medicare program, it is prudent for Medicare to perform its traditional coverage analysis for appropriate drugs and biologicals as it does for all other items and services to ensure that it only pays for those products that are clinically effective. For drugs and biologicals, Medicare will continue to use FDA approval as a default for a reasonable and necessary determination of an FDA-approved indication unless CMS decides otherwise. CMS may choose to perform a reasonable and necessary determination in several circumstances, including, but not limited to the following: the drug or biological in question represents a novel, complex or controversial treatment, may be costly to the Medicare program, may be subject to overutilization or misuse, or received marketing approval based on the use of surrogate outcomes.

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 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. 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 pass-through payments will exceed the applicable percentage but also to determine the appropriate reduction to the conversion factor.

In the August 9, 2002 proposed rule, we describe in detail the methodology we would use to make an estimate of pass-through spending in 2003 (67 FR 52117 through 52118). Very generally, after projecting 2003 pass-through spending for the groups of devices, drugs, biologicals, and radiopharmaceuticals as described in the proposed rule, we would calculate total projected 2003 pass-through spending as a percentage of the total (that is, Medicare and beneficiary payments) projected payments under OPPS to determine if the pro rata reduction would be required.

Below is a table showing our current estimate of 2003 pass-through spending based on information available at the time the table was developed. In the August 9, 2002 proposed rule we indicated that we were uncertain whether pass-through spending in 2003 will exceed $467 million or 2.5 percent of total estimated OPPS spending because we had not yet completed the estimate of pass-through spending for a number of drugs. We invited comments on the methodology we proposed to use to determine if a pro rata reduction would be necessary as well as the assumptions shown in Table X of the August 9, 2002 proposed rule that included anticipated utilization and utilization not yet determined.

We received several comments on this proposal, which are summarized below.

Estimates of Pass-Through Spending

Comment: A device manufacturer stated that it would be premature to impose pro rata reductions before we accurately account for an APC's device offset amount.

Response: Where applicable we have applied offset amounts to APCs with device categories for determining the final estimate of 2003 pass-through spending.

Comment: Many commenters said that there should be no pro rata reduction because we did not present the cost and utilization data that would be used to determine if the criteria for a reduction were met. Some commenters said that the pro rata reduction is discretionary and that we should not impose one because of the magnitude of the decreases for APCs that require expensive devices and the decreases in APCs for drugs (as compared to the pass-through payment). Some commenters said that our proposed projections overestimated the volumes that could be expected to occur in 2003.

Response: Section 1833(t)(6)(E)(i) of the Act requires that the Secretary estimate the total pass-through payments to be made for the forthcoming year (which allows us to determine the amount of the conversion factor for the forthcoming year) and to the extent the estimate exceeds the statutory limit, reduce the amount of each pass-through payment. For 2003,

the statutory limit is 2.5 percent of total estimated program payments. In the August 9, 2002 proposed rule, we provided our best estimate at that time of pass-through payments for the drugs and devices for which we expected to make pass-through payments in 2003, and we explained our methodology for determining the estimate for the final rule. We provided a list of the devices and drugs we either knew would be paid under pass-through next year or which we believed may be paid as pass-through items in 2003.

We have refined and finalized our estimate of pass-through spending in 2003 and, for the reasons discussed below, we have determined that no pro rata reduction will be required in 2003. Moreover, as discussed below the estimate falls under the statutory limit of 2.5 percent. Therefore, the conversion factor has been increased.

Comment: A commenter disagreed with the 2003 payment estimates in Table X of the August 9, 2002 proposed rule for the diagnostic and therapeutic radiopharmaceutical agents, IN–111 Zevalin and Y–90 Zevalin. The commenter estimated the number of patients receiving this therapy in the outpatient department setting in 2003 at approximately 2,500 for both the diagnostic and therapeutic portions, instead of the 9,000 that we projected in our August 9, 2002 proposed rule. The commenter further stated that the payment per patient for the Y–90 Zevalin therapy should be based on 40 mCi, the amount required in the preparation of the dose.

Response: Since publication of the August 9, 2002 proposed rule, we have determined that the appropriate payment mechanism for IN–111 Zevalin and Y–90 Zevalin is through the new technology APCs, rather than through the transitional pass-through payment methodology. Zevalin began receiving pass-through payment as a hospital outpatient service in 2002 as a radiopharmaceutical drug. After careful reexamination of Zevalin, we have determined that Zevalin is not a drug and therefore does not qualify for a pass-through payment.

Section 1861(t)(1) provides that the terms drugs and biologicals ''include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in [one of several pharmacopoeias] (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.'' A careful reading of this statutory language convinces us that inclusion of an item in, for example, the USPDI (as Zevalin is included, as a biological), does not necessarily mean that the item is a drug or biological. Inclusion in such reference (or approval by a hospital committee) is a necessary condition for us to call a product a drug or biological, but it is not enough. Rather, if we are to call a product a drug or a biological for our purposes, CMS must still make its own determination that the product is a drug or biological. In the case of Zevalin, we have determined that Zevalin is not a drug or a biological.

Zevalin consists of a radioactive isotope that is delivered to its target tissue by a monoclonal antibody. Because of the specific requirements associated with delivery of radioactive isotope therapy, any product containing a therapeutic radioisotope, including Y–90 Zevalin, will be considered to be in the category of benefits described under section 1861(s)(4) of the Act. Similarly, the appropriate benefit category for all diagnostic radiopharmaceuticals, including IN–111 Zevalin, is 1861(s)(3). We will consider neither diagnostic nor theraputic radiopharmaceuticals to be drugs as described in section 1861(t).

Thus, we have determined that the most appropriate Medicare benefit categories for IN–111 Zevalin and Y–90 Zevalin are as provided in sections 1861(s)(3) and (4) of the Act because they are a new diagnostic test and new radioactive isotope therapy, respectively. We will pay for IN–111 Zevalin under the New Technology APC 718 and for Y–90 Zevalin under the New Technology APC 725 until we have sufficient hospital charge data upon which to use in assigning these services to clinical APCs. Because we have decided that Zevalin does not qualify for transitional pass-through payments, we have not included the estimated payments for Zevalin in our revised estimates of total 2003 transitional pass-through payments.

We have based the determination of New Technology APCs for IN–111 Zevalin and Y–90 Zevalin on information received from the manufacturer and invoices made available to us, and we believe the resulting payment rates to hospitals should be adequate. We note that had we found it necessary to pay for these products as drugs, the average wholesale price alone could have exceeded $28,000 per treatment. We believe his pricing is excessive and that it would have placed an unnecessarily large burden on the Medicare Trust Funds. Had we found it necessary to treat these products as drugs, however, we could have invoked the authority of section 1833(t)(2)(E) to establish a more equitable payment rate.

A hospital may bill for the number of millicuries billed to them by a radiopharmacy or, if the hospital prepares Zevalin itself, the number of millicuries prepared for administration to the patient but, in either case, no more than 40 millicuries.

CMS has also undertaken a national coverage determination (NCD) for Zevalin, which has been approved by the Food and Drug Administration (FDA) to treat certain types of non-Hodgkin's lymphoma, to assure that the product is appropriately used in the Medicare program. A decision memorandum addressing the clinical uses of Zevalin to be covered by Medicare will appear on the CMS coverage Web site (*http://www.cms.hhs.gov/coverage*) soon after publication of this rule.

Comment: A drug company raised concerns about the relationship of epoetin alpha and darbepoetin alpha, two competing biologicals used for treatment of anemia. The commenter urged that CMS determine that the two products are substitutes with the same clinical effects and argued that the two should be paid, subject to an appropriate conversion ratio, at the same rate.

Response: Erythropoietin, a protein produced by the kidney, stimulates the bone marrow to produce red blood cells. In severe kidney disease, the kidney is not able to produce normal amounts of erythropoietin, and this leads to the anemia. Additionally, certain chemotherapeutic agents used in the treatment of some cancers suppress the bone marrow and cause anemia. Treatment with exogenous erythropoietin can increase red blood cell production in these patients and treat their anemia.

In the late 1980's, scientists used recombinant DNA technology to produce an erythropoietin-like protein called epoetin alpha. Epoetin alpha has exactly the same amino acid structure as the erythropoietin humans produce naturally, and, when given to patients with anemia, stimulates red blood cell production.

Two commercial epoetin-alpha products are currently marketed in the United States: Epogen™ (marketed by Amgen) and Procrit™ (marketed by Ortho Biotech). These products are exactly the same but are marketed under two different trade names. Both Epogen™ and Procrit™ are approved by FDA for marketing for the following conditions: (1) Treatment of anemia of chronic renal failure (including patients

on and not on dialysis), (2) treatment of Zidovudine-related anemia in HIV patients, (3) treatment of anemia in cancer patients on chemotherapy, and (4) treatment of anemia related to allogenic blood transfusions in surgery patients. Both products are given either intravenously or subcutaneously up to three times a week.

Amgen has recently developed a new erythropoietin-like product, darbepoetin alpha, which it markets as Aranesp™. Also produced by recombinant DNA technology, darbepoetin alpha differs from epoetin alpha by the addition of two carbohydrate chains. The addition of these two carbohydrate chains affects the biologic half-life. This change, in turn, affects how often the biological can be administered, which yields a decreased dosing schedule for darbepoetin alpha by comparison to epoetin alpha. Amgen has received FDA approval to market Aranesp™ for treatment of anemia related to chronic renal failure (including patients on and not on dialysis) and for treatment of chemotherapy-related anemia in cancer patients.

Because darbepoetin alpha has two additional carbohydrate side-chains, it is not structurally identical to epoetin alpha. However, the two products are functionally equivalent: In this case, both products use the same biological mechanism to produce the same clinical result, stimulation of the bone marrow to produce red blood cells. Thus, Epogen™, Procrit™, and Aranesp™ are all functionally equivalent.

These biologicals are dosed in different units. Epoetin alpha is dosed in Units per kilogram (U/kg) of patient weight and darbepoetin alpha in micrograms per kilogram (mcg/kg). The difference in dosing metric is due to changes in the accepted convention at the time of each product's development. At the time epoetin alpha was developed, biologicals (such as those developed through recombinant DNA) were typically dosed in International Units (or Units for short), a measure of the product's biologic activity. They were not dosed by weight (for example, micrograms) because of a concern that weight might not accurately reflect their standard biologic activity. The biologic activity of such products can now be accurately predicted by weight, however, and manufacturers have begun specifying the doses of such biologicals by weight. No standard formula exists for converting amounts of a biologic dosed in Units to amounts of a drug dosed by weight.

In clinical practice, CMS recognizes that no strict method of converting an epoetin alpha dose to a darbepoetin alpha dose exists. There are general guidelines for conversion, and clinicians modify the dose based on the patient's hematopoietic response. For developing a payment policy, however, it is feasible to establish a method of converting the dose of each of these drugs to the other.

As part of the process to define a conversion ratio between these biologicals, CMS held a series of meetings with both Amgen and Ortho Biotech. Both companies provided substantial written and published information. We reviewed the Food and Drug Administration labeling for each product (Epogen™, Procrit™, and Aranesp™). We also hired an independent contractor to review the available clinical evidence, and we performed an internal review of this evidence as well. The body of literature reviewed included 40 scientific articles culled from references submitted by the companies as well as a Medline literature search. CMS took into consideration both published and unpublished studies as well as abstracts, conference reports, and materials provided by the two companies.

In selecting articles for review, CMS sought studies that (1) provided a ''head-to-head'' comparison of epoetin alpha to darbepoetin alpha either in patients with chronic kidney disease (on or not on dialysis) or in cancer patients with chemotherapy-induced anemia, and (2) in which an appropriate outcome measure was used. In the absence of such data, we also considered clinical studies that either compared both products to each other or that linked the dose of a particular product with an appropriate health outcome measure.

CMS's identification of a conversion ratio between the dosages of these two products, darbepoetin alpha and epoetin alpha, is solely for the purpose of developing a Medicare payment policy. It is not meant to imply or suggest what should be done for individual patients in clinical practice. In addition, by using a conversion ratio CMS is not attempting to establish a lower or upper limit on the amount of either biological a physician can prescribe to a patient. CMS expects that physicians will continue to prescribe these biologicals based on the needs of individual patients. In terms of payment, however, CMS considers these biologicals to be functionally equivalent (even if structurally different), and, therefore, will establish an equitable payment policy that relates dosage of the agents to each other.

In our review, we placed the greatest emphasis on published, high quality clinical studies and looked for the best possible estimates based on an evaluation of the dosing of each product that, on average, produced the same clinical response. Based on our own review of the evidence, our consultation with the independent contactor who also reviewed the evidence, and our discussions with Amgen and Ortho Biotech, CMS concludes that an appropriate conversion ratio for the purposes of a payment policy is to 260 International Units of epoetin alpha to one microgram of darbepoetin alpha (260:1).

We think that improved information from clinical trials involving ''head-to-head'' comparisons of these two products could help us insure our policy is correct and if necessary update this policy in the future. In this vein, the National Cancer Institute has been directed to work with CMS to quickly develop and sponsor a trial or trials to evaluate the appropriate conversion ratio between these products for the purpose of Medicare pricing. We expect this project to be completed during the cycle for development of the 2004 OPPS update regulation. If we can estimate a more accurate conversion ratio based on this study or from our review of our own payment data, we will make a change to reflect this ratio so as soon as practicable.

We proposed that transitional pass-through payments for epoetin alpha end at the end of this calendar year, and that payment be made in calendar year 2003 in a separate, unpackaged APC. We are adopting these policies for the final rule.

We had proposed to continue transitional pass-through payments for darbepoetin alpha. We accept, however, the comment suggesting that these two biologicals should be paid at the same rate. As noted above, the products are almost identical; nevertheless there is a great disparity in their costs. In this situation, we believe it is appropriate for us to rely on our authority in section 1833(t)(2)(E) of the Social Security Act to make an adjustment we determine ''necessary to ensure equitable payments.'' We do not believe it would be equitable or an efficient use of Medicare funds to pay for these two functionally equivalent products at greatly different rates. We would package these two biologicals into the same APC, but the difference in dosage metrics makes this step technically impossible if we are to maintain the ability to pay on the basis of the actual dose used. Consequently, they will be in separate APCs but paid at equivalent rates. The 2003 payment rate for non-ESRD epoetin alpha is established as $9.10 per 1000 Units elsewhere in this

rule. We employ the conversion ratio of 260:1 to establish the 2003 payment rate for darbepoetin alpha as $2.37 per 1 microgram. Because this payment rate equals the payment rate for epoetin alpha (albeit expressed in different units), we reduce the transitional pass-through payment for darbepoetin alpha to zero.

An alternative line of reasoning would produce the same result. Section 1833(t)(6)(A) of the Social Security Act distinguishes between ''current'' and ''new'' biologicals. Epoetin alpha is a ''current'' biological. Since April 2002, we have treated darbepoetin alpha as a ''new'' biological. However, section 1833(t)(6)(A)(iv) sets forth the criteria that must be met for a biological to be considered ''new.'' One criterion is that the biological is not described by any item described in clauses (i), (ii) or (iii) of section 1833(t)(6)(A) of the Act, which define ''current'' drugs, biologicals, and devices. Given the determination stated above that these products are functionally equivalent, we believe that darbepoetin alpha is already described by epoetin alpha, a ''current'' biological. Because darbepoetin alpha is functionally equivalent to epoetin alpha, we believe we could conclude that it would be most appropriate to consider darbepoetin alpha a ''current'' biological. In that event, it would not qualify for a pass-through payment as a ''new'' biological. Accordingly, under this analysis, we would terminate the duration of transitional pass-through payment eligibility for darbepoetin alpha on December 31, 2002, and pay for it in a fashion comparable to other products that lose eligibility for transitional pass-through status on that date. More particularly, we would pay it equivalently to epoetin alpha.

Beneficiary copayments are unchanged as a result of the change in payment for darbepoetin alpha, because under this rule the copayment amount for both biologicals would have equaled that calculated for epoetin alpha in any case.

This change is budget neutral. As a result of this change, our estimate of total transitional pass-through payments is smaller than it would otherwise have been. The percentage we have reduced the conversion factor to compensate for transitional pass-through spending is accordingly smaller, and in a budget neutral fashion payment rates for other services are correspondingly higher.

We do not expect to make nationally-applicable determinations of similarity of drugs or biologicals, such as that discussed above, on a routine basis. We regard this situation as unusual, distinguished by the very strong similarity of the two products and by the size of the potential effects on the Medicare program. We thus believe that making this determination and insuring comparable payment is justified in this particular instance.

Comment: Commenters from pharmaceutical manufacturers, trade associations, and a provider of oncology services raised concern over the methods used to estimate 2003 pass-through payments for drugs. The primary concern was that we overestimated pass-through spending for 2003, and as a result would trigger pro rata reductions in pass-through payments for drugs appearing on Table X.

Some commenters suggested that we refine our estimation procedures by utilizing alternative modeling techniques and by using data from claims experience. Several of the comments included, in depth, data analysis along with models used to predict pass-through drug spending for calendar year 2003. Spending estimates ranged from $213 million to $441 million dollars.

Other commenters objected to the techniques used to estimate pass-through spending for future products, those items first eligible for pass-though payments in April 2003 or later. A manufacturer's association objected to the use of drugs eligible for pass-through payment beginning in January 1, 2003 as the basis of a forecast of drugs likely to acquire pass-through statusthroughout the remainder of the year. This objection stems from what the association views as the lack of similarities between drugs first eligible for pass-through payments on January 1, 2003 and those eligible later in the year. Further, they object to estimating any additional pass-through payments when it is not clear whether or not a product will be added to the list during 2003.

Another commenter proposed the use of a more sophisticated model based on drugs currently in the FDA pipeline to be used to project spending of drugs first eligible for pass-through payment between April and December 2003.

Other commenters objected to our estimates for specific drugs.

Response: We have made a number of changes in response to these comments and in the course of our efforts to complete and refine our preliminary estimates. We have removed several items from the list of 2003 pass-through items that appeared in our August 9, 2002 proposed rule and thus from our final estimates of 2003 pass-through payments. These include IN–111 Zevalin and Y–90 Zevalin, as noted above. FDG (HCPCS C1775; APC 1775) meets the statutory definition of a current radiopharmaceutical and has been receiving pass-through payments. Because we have decided that the pass-through status of current radiopharmaceuticals will not continue past December 31, 2002, pass-through payment status for FDG will end on January 1, 2003. Because a separate code for FDG did not exist until April 2002, we do not have discrete hospital charge data upon which to calculate a median cost for FDG. For transition purposes in 2003, we will pay separately for this supply based on an estimated acquisition cost of 71 percent applied to the 2002 payment rate.

We address below several other issues that arose during our refinement of Table X in the proposed rule. We proposed to continue pass-through payment status for TC 99M oxidronate under HCPCS C1058. However, following publication of the August 9, 2002 proposed rule, we determined that this drug was also represented by HCPCS code Q3009. Under HCPCS code Q3009, this radiopharmaceutical agent has received pass-through payment status for at least 2 years, and will no longer be eligible for pass-through payment under either HCPCS code Q3009 or C1058 beginning on January 1, 2003. As proposed, we are packaging the cost of Q3009 into the procedures with which the code was billed.

Two other HCPCS codes representing radiopharmaceutical agents were inadvertently included in the list of 2003 pass-through drugs in the proposed rule. HCPCS codes C1064 and C1065 were add-on codes used to bill for an additional mCi of I–131. These codes, along with the related HCPCS code C1188 and C1348, which are used to report an initial 1–5 or 1–6 mCi, respectively, will no longer be eligible for pass-through payment on January 1, 2003.

Table 9 contains the final list of items that are eligible for pass-through payments in 2002 and will remain eligible in 2003. Table 9 also contains items that have been approved for pass-through payments beginning in 2003.

It does not contain categories of devices or drugs for which pass-through applications are still pending at the time of issuance of this final rule or for which applications have yet to be received.

We used the following methodology to estimate the pass-through payments for 2003.

1. Devices eligible in 2002 [Device categories beginning July 1, 2002 (C1783, C1888, C1900)] that will continue in 2003: We used manufacturers' retail prices along with

claims utilization estimated for 2003 by our clinical staff, based on our claims data and coding and projected utilization information supplied in the applications. No device offsets were applicable.

2. Drugs eligible in 2002 that will continue in 2003: We used the July 2002 Redbook prices to determine the AWP, which we used in combination with our ratios for establishing estimated acquisition costs to derive pass-through payments for drugs in 2003. We determined the volume for pass-through drugs by soliciting manufacturer estimates of volume for the Medicare population where possible and relying upon a commenter's estimates for the volumes of other drugs.

3. Devices eligible in January 2003: We used manufacturers' retail prices along with claims utilization estimated for 2003 by our clinical staff, based on our claims data and coding and projected utilization information supplied in the applications. We applied offsets to procedures associated with devices that mapped to APCs with offsets.

4. Drugs eligible in January 2003: We used the July 2002 Redbook prices to determine the AWP which we used in combination with our ratios for establishing estimated acquisition costs to derive pass-through payments for drugs in 2003. We determined the volume for pass-through drugs by soliciting manufacturer estimates of volume for the Medicare population where possible and relying upon a commenter's estimates for the volumes of other drugs.

5. Devices eligible in 2001 and will continue in 2003: We used manufacturers' retail prices along with claims utilization for the 12 months that ended March 31, 2002, increased to 2003 by the growth rate provided by our actuary.

Our final estimate of transitional pass-through spending for 2003 also includes projected spending for items that have not yet been approved for 2003. We had proposed to base our estimate of spending for such items on items that have been newly approved for January 1, 2003. In response to comments, we have based our projection for items that will be approved later in 2003 on items that were newly approved for October 1, 2002 and January 1, 2003. We have based our estimate on the two most recent quarters of approval because we anticipate a higher volume of pass-through approvals compared to early 2002 for two reasons. First, we began paying for categories of devices on April 1, 2001. The vast majority of items in use at that time, as well as newly FDA approved items, could receive pass-through payments under a category code. We received, and subsequently approved, a relatively small number of pass-through applications in the first half of 2002. Consequently, we based our projection of spending for items that will be determined eligible for pass-through status in 2003 based on items determined eligible for October 1, 2002 and items determined eligible or expected to be determined eligible for January 1, 2003.

In summary, we estimate that pass-through spending in 2003 will approximate $427.4 million. We believe that pass-through spending in 2003 will break out into the following categories for 2003:

TABLE 9.—ESTIMATE OF PASS-THROUGH SPENDING IN 2003

HCPC	APC	Drug Biological	2003 Pass-through payment portion	2003 Estimated utilization	2003 Anticipated pass-through payment
Existing Pass-through Drugs/biologicals					
A9700	9016	Echocardiography Contrast	$30.00	423,220	12,696,607
J9017	9012	Arsenic Trioxide	$7.92	4,047	32,054
J0587	9018	Botulinum toxin type B	$2.22	350,000	777,000
J0637	9019	Caspofugen acetate, 5 mg	$8.64	98,950	854,928
J9010	9110	Alemtuzumab, per 10mg/ml	$129.15	11249.19861	1,452,834
C9111	9111	Injectin Bivalrudin, 250 mg vial	$100.50	38,549	3,874,219
C9112	9112	Perflutren lipid micro, 2 ml	$1.25	12,676,293	15,845,366
C9113	9113	Inj Pantoprazole sodium, vial	$5.76	20,000	115,200
J2324	9114	Nesiritide, per 1.5 mg vial	$36.48	48,000	1,751,040
J3487	9115	Zoledronic acid, 2 mg	$102.77	228,000	23,431,560
C9200	9200	Orcel, per 36 cm2	$286.80	1,000	286,800
C9201	9201	Dermagraft, per 37.5 sq cm	$145.92	4,770	696,038
C9116	9116	Ertapenum sodium	$11.45	8,902	101,928
C9119	9119	Pegfilgrastim	$708.00	102,645	72,672,864
J9219	7051	Leuprolide acetate implant	$1,364.16	373	508,493
Pass-through Drugs/Biologicals Effective January 2003					
C9120	9120	Faslodex	$22.13	9,690	214,440
C9121	9121	Argatroban	$3.60	50,000	180,000
Existing Pass-through Devices					
C1765	1765	Adhesior barrier		224	110,880
C2618	2618	Probe, cryoablation		752	150,400
C1783	1783	Ocular implant, aqueous drainage dev		2,042	1,327,300
C1888	1888	Endovascular non-cardiac ablation catheter		208	150,800
C1900	1900	Lead, left ventricular coronary venous		2,042	4,084,000
Pass-through Devices Effective January 2003					
C2614	2614	Brachytherapy solution/liquid,I–125		100	840,000
C2632	2632	Percutaneous Lumbar Discectomy Probe		612	1,190,340

TABLE 9.—ESTIMATE OF PASS-THROUGH SPENDING IN 2003—Continued

HCPC	APC	Drug Biological	2003 Pass-through payment portion	2003 Estimated utilization	2003 Anticipated pass-through payment
Other Items Expected to Be Determined Eligible for 2003					
.....	.....	Spending for future approved drugs	.....	.....	234,581,267
.....	.....	Spending for future approved devices	.....	.....	49,519,559
.....	.....	Total Spending for Pass-through Drugs/biologicals, and devices 2003.	.....	.....	427,445,917

Our total 2003 estimate of $427.4 million is 2.3 percent of total estimated program payment. We proposed to reduce the conversion factor by 2.5 percent to account for pass-through spending. Since our estimate is now below 2.5 percent, we have adopted a reduction of 2.3 percent to the conversion factor in accord with our estimate of pass-through payments. Our final assumptions used to create the estimate are shown in Table 9 above.

C. Expiration of Transitional Pass-Through Payments in Calendar Year 2003 for 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 proposed that 95 device categories currently in effect will expire effective January 1, 2003. Our proposed payment methodology for devices that have been paid by means of pass-through categories, but for which pass-through status will expire effective January 1, 2003, is discussed in the section below.

Although the device category codes became effective on April 1, 2001, many 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, or 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,) To establish the expiration date for the category codes listed in Table 10, we determined when item-specific devices that are described by the categories were first made effective for pass-through payment before the implementation of device categories. These dates are listed in Table 7 in the column entitled ''Date First Populated.'' We proposed to base the expiration date for a device category on the earliest effective date of pass-through status for any device that populates that category. Thus, the 95 categories for devices that will have been eligible for pass-through payments for at least 2 years as of December 31, 2002 would not be eligible for pass-through payments effective January 1, 2003.

Below is Table 7, which includes a comprehensive list of all pass-through device categories effective on or before July 1, 2002 with the date that devices described by the category first became effective for payment under the pass-through provisions and their respective proposed expiration dates.

TABLE 10.—LIST OF PASS-THROUGH DEVICE CATEGORIES WITH EXPIRATION DATES

	HCPCS codes	Category long descriptor	Date first populated	Expiration date
1	C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable).	8/1/00	12/31/02
2	C1765	Adhesion barrier	10/01/00–3/31/01; 7/1/01	12/31/03
3	C1713	Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable).	8/1/00	12/31/02
4	C1715	Brachytherapy needle	8/1/00	12/31/02
5	C1716	Brachytherapy seed, Gold 198	10/1/00	12/31/02
6	C1717	Brachytherapy seed, High Dose Rate Iridium 192	1/1/01	12/31/02
7	C1718	Brachytherapy seed, Iodine 125	8/1/00	12/31/02
8	C1719	Brachytherapy seed, Non-High Dose Rate Iridium 192	10/1/00	12/31/02
9	C1720	Brachytherapy seed, Palladium 103	8/1/00	12/31/02
10	C2616	Brachytherapy seed, Yttrium-90	1/1/01	12/31/02
11	C1721	Cardioverter-defibrillator, dual chamber (implantable)	8/1/00	12/31/02
12	C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable).	8/1/00	12/31/02
13	C1722	Cardioverter-defibrillator, single chamber (implantable)	8/1/00	12/31/02
14	C1888	Catheter, ablation, non-cardiac, endovascular (implantable)	7/1/02	12/31/04
15	C1726	Catheter, balloon dilatation, non-vascular	8/1/00	12/31/02
16	C1727	Catheter, balloon tissue dissector, non-vascular (insertable)	8/1/00	12/31/02
17	C1728	Catheter, brachytherapy seed administration	1/1/01	12/31/02
18	C1729	Catheter, drainage	10/1/00	12/31/02
19	C1730	Catheter, electrophysiology, diagnostic, other than 3D mapping (19 or fewer electrodes).	8/1/00	12/31/02
20	C1731	Catheter, electrophysiology, diagnostic, other than 3D mapping (20 or more electrodes).	8/1/00	12/31/02
21	C1732	Catheter, electrophysiology, diagnostic/ablation, 3D or vector mapping.	8/1/00	12/31/02
22	C1733	Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, other than cool-tip.	8/1/00	12/31/02

TABLE 10.—LIST OF PASS-THROUGH DEVICE CATEGORIES WITH EXPIRATION DATES—Continued

	HCPCS codes	Category long descriptor	Date first populated	Expiration date
23	C2630	Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, cool-tip.	10/1/00	12/31/02
24	C1887	Catheter, guiding (may include infusion/perfusion capability)	8/1/00	12/31/02
25	C1750	Catheter, hemodialysis/peritoneal, long-term	8/1/00	12/31/02
26	C1752	Catheter, hemodialysis/peritoneal, short-term	8/1/00	12/31/02
27	C1751	Catheter, infusion, inserted peripherally, centrally or midline (other than hemodialysis).	8/1/00	12/31/02
28	C1759	Catheter, intracardiac echocardiography	8/1/00	12/31/02
29	C1754	Catheter, intradiscal	10/1/00	12/31/02
30	C1755	Catheter, intraspinal	8/1/00	12/31/02
31	C1753	Catheter, intravascular ultrasound	8/1/00	12/31/02
32	C2628	Catheter, occlusion	10/1/00	12/31/02
33	C1756	Catheter, pacing, transesophageal	10/1/00	12/31/02
34	C2627	Catheter, suprapubic/cystoscopic	10/1/00	12/31/02
35	C1757	Catheter, thrombectomy/embolectomy	8/1/00	12/31/02
36	C1885	Catheter, transluminal angioplasty, laser	10/1/00	12/31/02
37	C1725	Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability).	8/1/00	12/31/02
38	C1714	Catheter, transluminal atherectomy, directional	8/1/00	12/31/02
39	C1724	Catheter, transluminal atherectomy, rotational	8/1/00	12/31/02
40	C1758	Catheter, ureteral	10/1/00	12/31/02
41	C1760	Closure device, vascular (implantable/insertable)	8/1/00	12/31/02
42	L8614	Cochlear implant system	8/1/00	12/31/02
43	C1762	Connective tissue, human (includes fascia lata)	8/1/00	12/31/02
44	C1763	Connective tissue, non-human (includes synthetic)	10/1/00	12/31/02
45	C1881	Dialysis access system (implantable)	8/1/00	12/31/02
46	C1764	Event recorder, cardiac (implantable)	8/1/00	12/31/02
47	C1767	Generator, neurostimulator (implantable)	8/1/00	12/31/02
48	C1768	Graft, vascular	1/1/01	12/31/02
49	C1769	Guide wire	8/1/00	12/31/02
50	C1770	Imaging coil, magnetic resonance (insertable)	1/1/01	12/31/02
51	C1891	Infusion pump, non-programmable, permanent (implantable)	8/1/00	12/31/02
52	C2626	Infusion pump, non-programmable, temporary (implantable)	1/1/01	12/31/02
53	C1772	Infusion pump, programmable (implantable)	10/1/00	12/31/02
54	C1893	Introducer/sheath, guiding, intracardiac electrophysiological, fixed-curve, other than peel-away.	10/1/00	12/31/02
55	C1766	Introducer/sheath, guiding, intracardiac electrophysiological, steerable, other than peel-away.	1/1/01	12/31/02
56	C1892	Introducer/sheath, guiding, intracardiac electrophysiological, fixed-curve, peel- away.	1/1/01	12/31/02
57	C1894	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser.	8/1/00	12/31/02
58	C2629	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, laser.	1/1/01	12/31/02
59	C1776	Joint device (implantable)	10/1/00	12/31/02
60	C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable).	8/1/00	12/31/02
61	C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable).	8/1/00	12/31/02
62	C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable).	8/1/00	12/31/02
63	C1900	Lead, left ventricular coronary venous system	7/1/02	12/31/04
64	C1778	Lead, neurostimulator (implantable)	8/1/00	12/31/02
65	C1897	Lead, neurostimulator test kit (implantable)	8/1/00	12/31/02
66	C1898	Lead, pacemaker, other than transvenous VDD single pass	8/1/00	12/31/02
67	C1779	Lead, pacemaker, transvenous VDD single pass	8/1/00	12/31/02
68	C1899	Lead, pacemaker/cardioverter-defibrillator combination (implantable).	1/1/01	12/31/02
69	C1780	Lens, intraocular (new technology)	8/1/00	12/31/02
70	C1878	Material for vocal cord medialization, synthetic (implantable)	10/1/00	12/31/02
71	C1781	Mesh (implantable)	8/1/00	12/31/02
72	C1782	Morcellator	8/1/00	12/31/02
73	C1784	Ocular device, intraoperative, detached retina	1/1/01	12/31/02
74	C1783	Ocular implant, aqueous drainage assist device	7/1/02	12/31/04
75	C2619	Pacemaker, dual chamber, non rate-responsive (implantable)	8/1/00	12/31/02
76	C1785	Pacemaker, dual chamber, rate-responsive (implantable)	8/1/00	12/31/02
77	C2621	Pacemaker, other than single or dual chamber (implantable)	1/1/01	12/31/02
78	C2620	Pacemaker, single chamber, non rate-responsive (implantable).	8/1/00	12/31/02
79	C1786	Pacemaker, single chamber, rate-responsive (implantable)	8/1/00	12/31/02
80	C1787	Patient programmer, neurostimulator	8/1/00	12/31/02
81	C1788	Port, indwelling (implantable)	8/1/00	12/31/02

TABLE 10.—LIST OF PASS-THROUGH DEVICE CATEGORIES WITH EXPIRATION DATES—Continued

	HCPCS codes	Category long descriptor	Date first populated	Expiration date
82	C2618	Probe, cryoablation	4/1/01	12/31/03
83	C1789	Prosthesis, breast (implantable)	10/1/00	12/31/02
84	C1813	Prosthesis, penile, inflatable	8/1/00	12/31/02
85	C2622	Prosthesis, penile, non-inflatable	10/1/01	12/31/02
86	C1815	Prosthesis, urinary sphincter (implantable)	10/1/00	12/31/02
87	C1816	Receiver and/or transmitter, neurostimulator (implantable)	8/1/00	12/31/02
88	C1771	Repair device, urinary, incontinence, with sling graft	10/1/00	12/31/02
89	C2631	Repair device, urinary, incontinence, without sling graft	8/1/00	12/31/02
90	C1773	Retrieval device, insertable	1/1/01	12/31/02
91	C2615	Sealant, pulmonary, liquid (Implantable)	1/1/01	12/31/02
92	C1817	Septal defect implant system, intracardiac	8/1/00	12/31/02
93	C1874	Stent, coated/covered, with delivery system	8/1/00	12/31/02
94	C1875	Stent, coated/covered, without delivery system	8/1/00	12/31/02
95	C2625	Stent, non-coronary, temporary, with delivery system	10/1/00	12/31/02
96	C2617	Stent, non-coronary, temporary, without delivery system	10/1/00	12/31/02
97	C1876	Stent, non-coated/non-covered, with delivery system	8/1/00	12/31/02
98	C1877	Stent, non-coated/non-covered, without delivery system	8/1/00	12/31/02
99	C1879	Tissue marker (implantable)	8/1/00	12/31/02
100	C1880	Vena cava filter	1/1/01	12/31/02

We considered a number of options on how to pay for devices after their pass-through payment status expires effective January 1, 2003. We held a Town Hall Meeting on April 5, 2002, to solicit recommendations on how to pay for drugs, biologicals, and devices once their eligibility for transitional pass-through payments expires in accordance with the time limits set by the statute. Interested parties representing hospitals, physician specialty groups, device and drug manufacturers and trade associations, and other organizations presented their views on these issues.

After carefully considering all the comments, concerns, and recommendations submitted to us regarding payment for devices and drugs and biologicals that would no longer be eligible for pass-through payments in 2003, we proposed to package the costs of medical devices no longer eligible for pass-through payment in 2003 into the costs of the procedures with which the devices were billed in 2001. (Our proposal to pay for pass-through drugs and biologicals whose pass-through status expires in 2003 is discussed below, in section IV.D.)

The methodology that we proposed to use to package pass-through device costs is consistent with the methodology for packaging that we describe in section III.B of this preamble. That is, 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 2001 charges for devices that will cease to be eligible for pass-through payment in 2003 into the changes for the HCPCS codes with which the devices were billed. We relied on the hospitals to correctly code their bills for all costs, including pass-through devices, using HCPCS codes and revenue centers as appropriate to describe the services that they furnished.

To prevent the loss of the device costs billed by hospitals through revenue centers in developing our relative weights for APCs, we proposed to package the costs of both the device ''C'' codes and the billed revenue centers, whichever appeared on the claim. At the time, we believed that this method would allow us to capture all device related costs billed by hospitals. See our discussion of charges for devices in section III.A.2 of the preamble for this issue.

We customarily allow a grace period for HCPCS codes that are scheduled for deletion. When we allow a grace period for deleted codes, we permit deleted codes to continue to be billed and paid for 90 days after the effective date of the changes that require their deletion. However, we proposed to not allow a grace period for expiring pass-through codes because permitting a grace period would result in pass-through payment for the items for which we proposed to cease pass-through payment effective with services furnished on or after January 1, 2003. Effective for services furnished on or after January 1, 2003, hospitals would submit charges for all surgically inserted devices in the supply, implant, or device revenue center that most appropriately describes the implant. Device costs will thus be packaged into and reflected in the costs for the procedure with which they are associated. Therefore, effective for services furnished on or after January 1, 2003, we proposed to reject line items containing a ''C'' code for a device category scheduled to expire effective January 1, 2003.

We received several comments on this proposal, which are summarized below.

General

Comment: A number of hospital organizations indicated they were pleased with our handling of the transitional pass-through payment provisions. The commenters supported our proposal to package into procedural APCs the costs of devices that are no longer eligible for pass-through payment. The commenters asserted that packaging of device costs into base APC payments minimized the confusion and complication of identifying pass-through codes for certain devices and eliminates special payment incentives to use pass-through devices. Provider organizations emphasized the difficult and complicated task of appropriate coding of pass-through items, especially during the transition from a brand-specific to device category system. These commenters also supported our proposal to include device costs from revenue centers in packaging device costs into APCs, to include all device costs.

Response: We appreciate these comments. We are adopting our proposed policy in this area as final for 2003.

Comment: A hospital organization proposed that we release the crosswalk we used to assign pass-through device costs to specific APCs, so that it can study the assignments made, out of concern that some APCs may receive inadequate payment rates.

Response: Our methodology did not involve a cross-walk, so we do not have

one available. Claims files we have made publicly available may be used to analyze where device costs were allocated.

Comment: A device manufacturer stated it conceptually agreed that costs of devices should be packaged into ''base'' APC rates of related procedures. However, it viewed as critical that 2003 payment rates appropriately and adequately capture device costs.

Response: We agree. As described elsewhere, we are adopting a number of changes in our methodology to help insure appropriate payments for procedures whose payment rates would otherwise have fallen significantly from 2002.

Comment: A hospital provider organization urged us to remain committed to the averaging process inherent in a prospective payment system, rather than seek to pay actual cost for elements of total costs, such as new technology. It opposed the imposition of additional administrative costs, for example, any required reporting of acquisition costs on claims, in order to ''fine tune'' pass-through payments or relative weights. It preferred a sample survey to any reporting of acquisition costs. It also preferred that hospitals be permitted to establish their charge structures separately from our payment policies. It recommended that we avoid overriding the hospital-specific cost-to-charge ratio in order to alter the ratios for new technology devices and not distort the PPS to pay for selected items.

Response: We appreciate this comment. We have no plans to require reporting of acquisition costs on claims. Although we intend to consider further improvements in our methods for determining OPPS payment rates in the future, we recognize that the importance of maintaining a well developed and coherent methodology.

Comment: A hospital provider organization recommended that we furnish a regulatory impact analysis that reflects the total change in payments that are estimated to occur that include outlier, pass-through and corridor payments and each of these items should be separately identifiable.

Response: We regret that we are unable to provide the level of detail the commenter requests in the impact analysis. We discuss the extent of our knowledge of accuracy of the pro rata reduction and fold in impact in 2002 in section VIII.

Comment: A commenter requested that we disclose how much the ''fold-in'' of device costs into procedure APC payments for 2002 and the pro rata reduction imposed during 2002 over or under compensated hospitals for the new technology devices and drugs. This organization contended that we overestimated the amount of pass-through payments in 2002, when compared to actual payments, and thus arbitrarily removed some $400 million from an already underfunded OPPS.

Response: We do not have a revised estimate of transitional pass-through spending for 2002 available at this time. We note that the lack of a pro rata reduction in 2001 may have resulted in higher than expected spending in that year. In either case, the statute does not provide for any retrospective adjustments, either up or down, if the Secretary's estimate of transitional pass-through spending made in advance of the start of the relevant calendar year, and which is used to determine whether a pro rata reduction is necessary and if so how large it must be, later proves too high or too low.

Expiration of Device Categories

Comment: A large number of commenters questioned the adequacy of rates proposed for 2003 for APCs involving devices now paid transitional pass-through payments in instances where the device categories expire. Many of these commenters provided information about manufacturers' prices for these devices.

Response: We are also concerned about the adequacy of these payment rates. We have reviewed the information provided, and it has helped guide us in determining our final policies for 2003. As discussed elsewhere in this preamble, we have used more recent data, carefully selected appropriate claims for use in relative weight calculations, and adopted dampening provisions to mitigate the reduction in payment rates that might otherwise have occurred.

Comment: Some commenters recommended that we delay expiration of transitional pass-through device categories until we collect more accurate data. A device manufacturer suggested that we extend the pass-through payment period for another year to allow time to study ways of capturing hospital costs, to improve accuracy of APC rates.

Response: For devices that have been paid in 2000, we cannot extend the pass-through payment as suggested, because this would violate the statutory provision that limits pass-through payments for at least 2 but not more than 3 years. Section 1833(t)(6)(B)(iii)(II) states that a category of devices shall be in effect for a period of at least 2 but not more than 3 years, which begins in the case of the categories initially implemented on April 1, 2001, ''on the first date on which payment was made * * * for any device described by such category (including payments made during the period before April 1, 2001.'' We cannot extend the transitional pass-through payments in order to collect more data.

Comment: A number of organizations recommended that we continue transitional pass-through payment status for an additional year for one or more of several categories that were first populated with devices on January 1, 2001. One commenter recommended that we continue pass-through payments for all current device categories until July 31, 2003 and through December 31, 2003 for items in categories first populated as of January 1, 2001, stating that we make mid-year changes to billing requirements and HCPCS codes. The commenter acknowledged that this may be burdensome, but stated that the benefit of paying appropriately outweighs the cost of revising rates in mid-year.

Response: We have reviewed these categories and do not see a marked difference between these categories and the other categories the eligibility of which is expiring. As a result, we do not believe it would be appropriate to continue transitional pass-through payment status for them beyond December 31, 2002.

Revising rates in mid-year is not generally part of Medicare rate-making policy and is not appropriate in this instance either. It is not only burdensome for this agency, it also burdens the providers and fiscal intermediaries, and it would add confusion to an already complex system.

Comment: Organizations recommended that we continue pass-through payment status for cardiac resynchronization ICDs devices through category C1882. We indicated that this category contains devices that first received transitional pass-through payments as of August 1, 2000. The commenter is concerned that this category, which is described as ''cardioverter-defibrillator, other than single or dual chamber,'' also includes a cardiac resynchronization ICD that was first eligible for transitional pass-through payments on January 1, 2001. The commenter suggested that in order to avoid any unfair competitive advantage among categories with competing technologies, we should extend pass-through payments for both C1882 and C2621, ''pacemaker, other than single or dual chamber,'' which includes cardiac pacemakers.

Response: We cannot extend the pass-through payment status for C1882. We believe the most appropriate step is to end these categories in tandem. Therefore, we will terminate transitional pass-through payments for these 2 categories simultaneously as of January 1, 2003.

Comment: A hospital organization requested clarification regarding the expiration of transitional pass-through device categories effective January 1, 2003. This commenter was confused by our stated proposal to delete 95 pass-through category codes as of January 1, 2003, yet Addendum B of the proposed rule shows these 95 codes as active codes with an OPPS status indicator of ''N'' (packaged). A number of commenters recommended that hospitals retain the option to code them and have the ''N'' status drive the payment, or in order to continue to report and track those devices.

Response: We intend on deleting these codes, with the line item use of the codes rejected. We clarify the status indicator in this final rule.

Comment: A hospital provider organization requested clarification on our proposal that hospitals submit charges for all surgically inserted devices in the supply, implant, or device revenue center that most appropriately describes the implant and that the device costs will then be packaged into and reflected in the costs for the procedure with which they are associated. It noted that we published clear requirements on what revenue codes were appropriate for reporting medical devices that had been granted pass-through status in Program Memorandum A–01–50. The organization stated that that this would constitute the appropriate revenue center list to use for these devices even though they are now packaged.

Response: In the proposed rule we indicated that effective for services furnished on or after January 1, 2003, hospitals would not bill a ''C'' code for devices that no longer qualify for pass-through payment, but would submit charges for surgically inserted devices in the supply, implant or device revenue center that most appropriately describes the implant. We agree with the commenter that the revenue codes listed in Program Memorandum A–01–50 will continue to constitute the appropriate revenue codes under which such devices must be billed, even when the devices are no longer eligible for pass-through payments.

Use of Codes for Expiring Categories After January 1, 2003

Comment: A commenter asked us to clarify the use of device HCPCS codes after their expiration dates. Commenters expressed concern that our proposed deletion of the pass-through codes of drugs and devices as of January 1, 2003 without a grace period would place a burden on hospitals. One commenter recommends that we change the status indicator to ''N'', that is, packaged with other services. One commenter stated that we should keep all C-codes in effect permanently, even without reimbursement. The commenter argues that this step would provide better tracking for providers and payers and eliminates the coding burden caused by deletion of codes.

Response: We proposed to delete the pass-through category codes for devices when the eligibility of the category for pass-through payments expires. Therefore, any claims that use these codes will be returned to providers. We proposed to reject the line item in the proposed rule. However, on further consideration and discussion within CMS, we decided that we must return the claim to the provider so that the provider may correctly place the charges for the device in a revenue center. This is important to ensure that the hospital receives any hold harmless, corridor or outlier payments that it is due. If we were to line item reject the deleted code and process the rest of the claim, then the hospital could be underpaid by the absence of payments that would result if the charges for the device were correctly reported. Given the frequency with which our data shows that providers fail to bill for the device (even when they could receive pass-through payment for it as discussed in section III.A.2 of the preamble), we believe that it is important that the claim be returned to the provider so that it can be corrected and resubmitted for payment.

Comment: A hospital organization agreed with our proposal not to have a 90-day grace period for C-codes scheduled for deletion, to prevent additions to the pass-through payment pool, which could then contribute to a pro rata reduction to other services.

Response: We agree. We believe it is necessary in this instance to forgo a grace period to prevent incorrect payments.

New Device Categories

Comment: A number of commentersprovided both supportive and critical comments to the August 9, 2002 proposed rule on our criteria for establishing new device categories for transitional pass-through payment. One commenter indicated that we have been reviewing and evaluating applications for new device categories even though we have not issued a final rule on this subject.

Response: We have summarized comments that we received timely in response to the November 2, 2001 interim final rule on the criteria, and these are addressed in section V of this final rule. We will take note of all comments as we evaluate the new device category process and any modifications to the process we might propose in the future. Our review of applications for device categories has been done under authority of the November 2, 2001 interim final rule.

Stent Categories C1874 and C1875

Comment: A number of commenters took issue with our interpretation of existing category limitation in evaluating applications for new pass-through device categories. They cited our discussion on drug-eluting stents, that is, that this new technology was described by existing categories C1874, stent, coated/covered with delivery system, and C1875, stent, coated/covered without delivery system. These commenters asserted that neither of the existing categories appropriately describes the drug-eluting stent technology. While they indicated that creating a new APC for drug-eluting stents is appropriate, they expressed concern that many existing categories are described in broad terms, thus potentially excluding other new technologies from additional categories. Examples of applications for ICDs and total joint implants were provided.

Response: We are making final our proposal for separate, procedure APCs for procedures involving drug-eluting stents. These stents will not be in a transitional pass-through category nor receive transitional pass-through payments. In the case of breakthrough therapies that may quickly achieve widespread distribution and that are sufficiently expensive to have a significant effect on hospitals, we may propose to create appropriate APCs, as we have done in this instance. The existing transitional pass-through device categories were deliberately specified in fairly broad terms in order to provide an appropriate balance between specificity and the reporting burden on hospitals.

DME Payment for Implantable Devices

Comment: One commenter, concerned about reduced payments for implantable devices, suggested that we define certain implantable devices as durable

medical equipment and/or prosthetics, for payment under the durable medical equipment fee schedule instead of the OPPS.

Response: The BBRA of 1999 changed the OPPS and durable medical equipment fee schedule (see sections 1833(t)(1)(B)(iii) and 1834(h)(4)(B) of the Act) so that implantable prosthetic devices delivered in the hospital outpatient setting must be paid through the OPPS, rather than on the durable medical equipment fee schedule.

Category C1765, Adhesion Barrier

Comment: A commenter claimed that one of our categories that we propose to continue pass-through payment in 2003, Adhesion Barrier (C1765), contains a product that was manufactured by a single company. The FDA asked the company to recall the product, and it has been off the market for more than a year. This commenter suggested that C1765 be removed from the APC system for 2003, since neither this nor equivalent products are on the market. If and when this or another similar product is reintroduced to the market, it should be considered for pass-through payment at that time.

Response: We will not remove category C1765 from active pass-through payment, which is scheduled to continue through December 31, 2003. C1765 is open to any product that fits the category description of adhesion barrier in accordance with the definition in Program Memorandum A–02–050, not only the product of the stated manufacturer.

Cochlear Implants

Comment: Numerous providers, including hospitals, ENT clinics, physicians, clinical audiologists and other commenters, protested our proposed payment rates for cochlear implant services. They questioned our data for 2001, saying insufficient claims data appear to be reported for the procedure or that the charges appear inappropriately low. Some providers requested an average payment of $3,000 for the surgery, plus the invoice cost of the device, some offering to include the manufacturer's invoice with their claims. Comments also included recommendations that we continue to pay for cochlear implants as pass-through payments for another year or more to develop more accurate claims data . A group of manufacturers also recommended that we issue written guidance to hospitals regarding the correct billing procedures for cochlear implants.

Response: We have attempted to mitigate the proposed reductions in payment rates resulting from the expiration of transitional pass-through device categories, of which cochlear implant is one . Transitional pass-through payments were first made for cochlear implants on August 1, 2000, before pass-through category L8614 was established. Therefore, we cannot provide another year or more of pass-through payments, because the statute limits pass-through payments to a period of at least 2 years but not more than 3 years. We feel the recommendation that we issue guidance to hospitals regarding the correct billing procedures for device related procedures, such as cochlear implants, may have merit, and we will consider providing further guidance in this area.

IOLs

Comment: A number of commenters expressed concern that the expiration of the transitional pass-through device category for new technology intraocular lenses (IOLs) on January 1, 2003 would result in inadequate payment for new technology lenses. These commenters recommended that a new APC be created to pay for the provision of these lenses, even though the incremental cost is low. These commenters also recommended that we create new categories of new technology IOL ''for additional payment similar to the provision applicable in ambulatory surgical centers. One commenter was concerned that we not allow the broad description of the current category C1780, ''lens, intraocular (new technology)'' to interfere with future intraocular lenses being eligible for pass-through payment.

Response: Regarding the adequacy of payment after the new technology IOL category expires, no specific data were provided by any commenters. However, we believe that the incremental cost of such lenses is low. We do not believe a change the APC for implanting new technology IOLs is warranted at this time.

Implantation of Neurostimulator (APC 222) and Electrode (APC 225)

Comment: A manufacturer and a number of medical centers commented that the proposed payments for implantation of a neurostimulator generator (APC 222) and electrode (APC 225) are inadequate. One of these commenters recommended that we delay the expiration of these pass-through categories for another year or two.

Response: The implantations of a neurostimulator generator and electrode have been paid via pass-through payment for devices since August 2000, and we proposed to retire the pass-through categories as of January 1, 2003. For devices that have been paid since August 2000, we cannot extend the pass-through payment for another year or two, as suggested, because this would violate the statutory provision that limits pass-through payments for at least 2 but not more than 3 years. Therefore, we are moving to prospective payment for these devices from the charge-based pass-through payments.

Dialysis Access Systems

Comment: A manufacturer of a dialysis access system asserted that the 2003 proposed reduction in payment rates for dialysis access would curtail patient access.

The commenter provided two suggestions regarding the expiring category code for dialysis access systems, C1881. One option suggested is for us to assign a unique HCPCS code for placement of the manufacturer's brand specific dialysis system and place it in a new or existing APC that has appropriate payment. This commenter contended that bundling C1881 within APC 115 will result in inadequate payment, because the device will be bundled with standard hemodialysis catheters and chemotherapy ports. The second option suggested is to extend pass-through payment status for category C1881. This commenter stated its dialysis system was approved for pass-through payment in August 2000, and there were limited sales and therefore claims in 2000 and the first half of 2001. Thus, this commenter expressed the opinion that there is approximately 1 year of data for this category, not the 2 to 3 years required.

Response: Regarding the option proposed by this commenter for assignment of a unique product-specific HCPCS code, we do not assign unique HCPCS codes for brand-specific devices. Section 1833(t)(6)(B) of the Act indicates that transitional pass-through status of devices is to be determined based on categories. HCPCS codes are generally assigned for procedures that are not adequately described by existing HCPCS codes. This device has had a temporary category code for roughly two and one-half years, and we believe there are sufficient data to measure its utilization and cost. Regarding this commenter's proposal to extend pass-through payment status for category C1881, we cannot, by law, extend the pass-through payment period beyond the 2 to 3 year period. Although the commenter asserted that there were only limited claims for pass-through payment for the device in 2000 and the first half of 2001, section 1833(t)(6)(B)(iii) of the