

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410 and 419

[CMS-1206-P]

RIN 0938-AL19

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: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In addition, it would describe proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. These changes would be applicable to services furnished on or after January 1, 2003. In addition, this rule proposes 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.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on Monday, October 7, 2002.

ADDRESSES: In commenting, please refer to file code CMS-1206-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1206-P,
P.O. Box 8018,
Baltimore, MD 21244-8018.

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

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

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

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

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

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

FOR FURTHER INFORMATION CONTACT:

Anita Heygster, (410) 786-0378--outpatient prospective payment issues;

Lana Price, (410) 786-4533--partial hospitalization and ESRD;

Gerald Walters, (410) 786-2070--payment suspension issues;

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security

Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call (410) 786-7197.

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Alphabetical List of Acronyms Appearing in the Proposed

Rule

ACEP	American College of Emergency Physicians
AMA	American Medical Association
APC	Ambulatory payment classification
AWP	Average wholesale price
BBA	Balanced Budget Act of 1997
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

BBRA	Balanced Budget Refinement Act of 1999
CCR	Cost center specific cost-to-charge ratio
CMHC	Community mental health center
CMS	Centers for Medicare & Medicaid Services (Formerly known as the Health Care Financing Administration)
CPT	(Physician's) Current Procedural Terminology, Fourth Edition, 2002, copyrighted by the American Medical Association
CSW	Clinical social worker
CY	Calendar year
DRG	Diagnosis-related group
DSH	Disproportionate Share Hospital
EACH	Essential Access Community Hospital
E/M	Evaluation and management
ERCP	Endoscopic retrograde cholangiopancreatography
ESRD	End-stage renal disease
FACA	Federal Advisory Committee Act
FY	Federal fiscal year
HCPCS	Healthcare Common Procedure Coding System
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICU	Intensive care unit

ICD-9-CM International Classification of Diseases, Ninth Edition, Clinical Modification

IME Indirect Medical Education

IPPS (Hospital) inpatient prospective payment system

LTC Long Term Care

MedPAC Medicare Payment Advisory Commission

MDH Medicare Dependent Hospital

MSA Metropolitan statistical area

NECMA New England County Metropolitan Area

OCE Outpatient code editor

OMB Office of Management and Budget

OPD (Hospital) outpatient department

OPPS (Hospital) outpatient prospective payment system

OT Occupational therapist

PHP Partial hospitalization program

PPS Prospective payment system

PPV Pneumococcal pneumonia (virus)

PRA Paperwork Reduction Act

RFA Regulatory Flexibility Act

RRC Rural Referral Center

RVUs Relative value units

SCH Sole Community Hospital

TEFRA Tax Equity and Fiscal Responsibility Act

USPDI United States Pharmacopoeia Drug Information

Comparison of Proposed 2003 Payment Rates to 2002 Payment Rates

The outpatient pass-through provisions of the BBRA and BIPA have been exceptionally difficult to implement, arguably the most complex and difficult in the history of the Medicare program. In CY 2002, the pass-through payments, and the APC rates were calculated on the best information available. This was often manufacturer list prices, which may not reflect not actual prices paid by hospitals. For CY 2003, far more data is available on the actual charges for hospital OPDs, and these are reflected in the rates in this proposed rule. In many cases these new rates are significantly different from CY 2003 rates, but they are based on actual hospital charges, and on far more complete data than were the CY 2002 rates. Nevertheless, CMS is actively seeking comment on all aspects of these rates, given the significant changes in the proposed rule, and the agency is open to making changes, perhaps significant, in the final rule based on comments.

The 2003 payment rates proposed in this proposed rule are, for many items and services, significantly higher or lower than the payment rates for the same items and services for 2002, particularly for APCs which use medical

devices, and for APCs for drugs that will no longer be eligible for pass-through status in 2003 and paid under separate APCs. Some proposed payments for 2003 are far lower than the 2002 payment amounts (and some are higher).

For example, as can be seen in Addenda A, the proposed rate for APC 0108 (Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads) shows a dramatic decrease in payment compared to the 2002 rate. This reduction for a number of APCs is of concern to us because of the potential impact on access to care. We invite public comment and suggestions on how to address the potential for adverse impact of these proposed changes.

The proposed 2003 payment rates reflect the use of updated data, as required by the statute, in calculating payment rates in accordance with the methodologies set forth in the statute and regulations. The proposed payment rates reflect mathematical calculations based on the latest available program data.

Our goal in this proposed rule is to explain the methodology and to solicit comments on our rate-setting methods and the effect on beneficiary access, provider participation and the fiscal integrity of the Medicare Trust Fund.

Devices

We believe that there are several factors that may explain the differences between the proposed payment amounts for 2003 and the payment amounts for 2002 (some, but not all of which, are significant).

First, we believe that the payment rates for the device related procedures for 2002 may in some cases have been higher than they would have been had actual hospital acquisition cost data been available for us to use. Specifically, because we lacked hospitals' cost data for devices, we used the best data available to us at the time which was manufacturer data regarding the hospitals' acquisition costs in providing the devices. We assumed that a device would be provided with a related procedure and packaged 75 percent of these manufacturer estimated costs for the devices into the APCs for the procedures.

The costs that we packaged in for some devices may have been higher than actual hospital acquisition costs. The differences between the 2002 payment rate and the lower 2003 proposed payments are based on our data sources. While the 2003 rates are based on 2001 hospital claims and the latest available cost report data, the 2002 rates are based on manufacturer data for devices. We use charges on the hospital claims data to estimate hospital costs. We

apply hospital-specific, department-specific cost-to-charge ratios (CCRs) from each provider's most recently submitted cost report to the charges to develop the estimate of costs. In most cases, the provider's most recently submitted cost report is from fiscal year 1999. An adjustment factor is applied in developing CCRs for cost reports that have not yet been settled, so that the CCRs will more closely reflect CCRs from a settled cost report.

Secondly, there may be problems in the data, particularly for coding of devices in 2001. As discussed later in this preamble, devices were to be coded using device specific C codes from the start of the OPPS on August 1, 2000 until the law changes required that we establish category codes by April 1, 2001. We then granted a grace period until July 1, 2001, during which we accepted both device specific codes and category codes. During a Town Hall meeting with the public on April 5, 2001, and in other contacts with hospitals (such as the open forum calls and visits to hospitals) we have been told that hospitals had difficulty in submitting proper HCPCS coding for services and for devices once OPPS began and that, in many cases, they did not bill for devices for which they should have claimed payment.

In some cases, hospitals were confused by the change from device specific codes to category codes; in other cases, the use of HCPCS codes was new and they had a long learning curve to learn how to use HCPCS codes. Our initial data analysis suggested that hospitals may not have billed for the devices using the device or category codes in all cases. If the charges were not on the claim, they would not have been picked up for calculation of the median cost for the service and the associated device, possibly resulting in a proposed payment rate for the APC that is inappropriately low and other rates that are inappropriately too high. However, based on our analysis which is described later, we believe that hospitals often showed the charges for the devices in the applicable revenue centers (such as, supplies) and that the charges for the devices often were on the claim, even if the HCPCS code was not.

We welcome public comments regarding these issues for these payment changes and proposals regarding how problems with claims data could be rectified for development of the final rule.

Drugs

As discussed later in this preamble, we propose to package the costs for lower cost drugs into the payment for

the APC in which they are used and to pay specialty drugs and high cost drugs under separate APCs. Some of the APCs for separately paid drugs also show significant reductions in payments compared to the pass-through payments made in 2002. Several factors may help place these decreases in perspective.

These changes result largely because the payment method for items in transitional pass-through payment status differs significantly from other services paid under the OPSS, and as items lose transitional pass-through payment status they are subject to a different payment method. In particular, a drug in transitional pass-through payment status is paid based on 95 percent of the average wholesale price for the drug, possibly subject to a uniform reduction.¹

In contrast, a drug not in transitional pass-through status is paid as are other services under the OPSS. The statute provides that services (other than transitional

¹ In 2002, we apply a uniform reduction to the transitional pass-through portion of payments for drugs with transitional pass-through status. As a result, the OPSS now pays hospitals about 72 percent of AWP for drugs in this status. The uniform reduction, as discussed in the March 1, 2002 final rule, is to comply with section 1833(t)(6)(E) of the Act, which limits the total projected amount of transitional pass-through payments for 2002 to 2.5 percent of projected total payments under the OPSS in 2002.

pass-through items) be paid on the basis of a service-specific relative weight multiplied by a conversion factor. The relative weight is determined based on the median hospital cost, where the cost on each claim is derived by multiplying the submitting hospital's charge by a cost-to-charge ratio (determined from the hospital's latest submitted cost report, usually from fiscal year 1999). We anticipate that a hospital's charges on particular services reflect, at least in relative terms, the hospital's resource use in providing that service.

Per the statute, the conversion factor was set at the initiation of the system to achieve budget neutrality relative to the prior system; it is updated each year by the rate of increase in the hospital market basket. This mechanism does reflect changes in input costs from the initial base, but the system is not rebased to reflect the absolute level of such costs.

This payment method was not intended to assure that hospitals, even on average, are reimbursed costs of particular services. In fact, because the conversion factor was calibrated to reflect prior reductions in hospital operating and capital costs that were built into

the baseline for overall program expenditures, the OPSS is not set to pay full costs to hospitals.²

Further, nothing in the payment method prescribed by the statute requires or anticipates that hospitals would be reimbursed full costs of purchased inputs such as drugs, just as it does not anticipate that hospitals would be reimbursed for the full cost of any other services they deliver.

The payment methods are set out in section 1833(t) of the Act. This section does not permit continuation of a pass-through payment (at 95 percent of AWP or some other level) for drugs losing their transitional pass-through status. This section permits the Secretary to specify APC groupings, and we are proposing in 2003 to continue to pay separately for certain drugs that had transitional pass-through status in 2002 and that are no longer eligible for pass-through status in 2003. These drugs would be in separate APCs, rather than being packaged into other, procedure-related APCs; the payment method would be the same relative-weight payment method used for other APCs.

² In fact, because of the effect of prior statutory reductions in payments, the OPSS system was calibrated at its initiation to pay only about 82 percent of hospital costs in the aggregate.

The resulting payment rates incorporate the best evidence we have regarding what hospitals charged in 2001. They may diverge, however, from payment rates based on the AWP, including those in use for 2002. As is discussed above, movement from pass-through payment rates to relative-weight based payment rates would be expected to lead to decreases in payments, even if AWP represented a reliable measure of hospital acquisition costs (As discussed above, we use hospital charges and hospital-specific, department-specific cost-to-charge ratios to estimate hospital costs. In most cases, cost-to-charge ratios are derived from 1999 cost reports).

However, we believe this outcome is also be due to deficiencies in AWP as a measure of hospital acquisition costs. AWP is not an accurate estimate of what providers actually pay for drugs. Studies undertaken over the past decade by the Office of the Inspector General, the Department of Justice, and the General Accounting Office that compare AWP with actual drug acquisition costs have consistently shown that published AWPs considerably exceed these costs (See "MEDICARE Payments for Covered Outpatient Drugs Exceed Providers' Costs", GAO-01-1118). Therefore, it is to be expected that the proposed 2003 APC payment rates based on median hospital costs for these drugs will

be lower than the 2002 payment rates for the same drugs that are based on AWP. The Administration has repeatedly stated its view that AWP inaccurately represents actual market pricing. The pass-through system pays based on AWP, creating further incentives for artificially high AWP listings. We believe the steep reductions in some drug prices reflect these incentives, and that the new rates more accurately reflect the actual acquisition costs for hospitals pay. Still, we are interested in soliciting comments on these costs, and the mechanisms to identify them.

I. Background

A. Authority for the Outpatient Prospective Payment System

When the Medicare statute was originally enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), enacted on August 5, 1997, added section 1833(t) to the Social Security Act (the Act) authorizing implementation of a PPS

for hospital outpatient services. The Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), enacted on November 29, 1999, made major changes that affected the hospital outpatient PPS (OPPS). The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554), enacted on December 21, 2000, made further changes in the OPPS. The OPPS was first implemented for services furnished on or after August 1, 2000.

B. Summary of Rulemaking for the Outpatient Prospective System

- On September 8, 1998, we published a proposed rule (63 FR 47552) to establish in regulations a PPS for hospital outpatient services, to eliminate the formula-driven overpayment for certain hospital outpatient services, and to extend reductions in payment for costs of hospital outpatient services. On June 30, 1999, we published a correction notice (64 FR 35258) to correct a number of technical and typographic errors in the September 1998 proposed rule including the proposed amounts and factors used to determine the payment rates.

- On April 7, 2000, we published a final rule with comment period (65 FR 18434) that addressed the provisions of the PPS for hospital outpatient services scheduled to be

effective for services furnished on or after July 1, 2000. Under this system, Medicare payment for hospital outpatient services included in the PPS is made at a predetermined, specific rate. These outpatient services are classified according to a list of ambulatory payment classifications (APCs). The April 7, 2000 final rule with comment period also established requirements for provider departments and provider-based entities and prohibited Medicare payment for nonphysician services furnished to a hospital outpatient by a provider or supplier other than a hospital unless the services are furnished under arrangement. In addition, this rule extended reductions in payment for costs of hospital outpatient services as required by the BBA and amended by the BBRA. Medicare regulations governing the hospital OPPS are set forth at 42 CFR part 419.

- On June 30, 2000, we published a notice (65 FR 40535) announcing a delay in implementation of the OPPS from July 1, 2000 to August 1, 2000. We implemented the OPPS on August 1, 2000.

- On August 3, 2000, we published an interim final rule with comment period (65 FR 47670) that modified criteria that we use to determine which medical devices are eligible for transitional pass-through payments. The August 3, 2000 rule also corrected and clarified certain

provider-based provisions included in the April 7, 2000 rule.

- On November 13, 2000, we published an interim final rule with comment period (65 FR 67798). This rule provided for the annual update to the amounts and factors for OPPS payment rates effective for services furnished on or after January 1, 2001. We implemented the 2001 OPPS on January 1, 2001. We also responded to public comments on those portions of the April 7, 2000 final rule that implemented related provisions of the BBRA and public comments on the August 3, 2000 rule.

- On November 2, 2001, we published a final rule (66 FR 55857) that announced the Medicare OPPS conversion factor for calendar year 2002. In addition, it described the Secretary's estimate of the total amount of the transitional pass-through payments for CY 2002 and the implementation of a uniform reduction in each of the pass-through payments for that year.

- On November 2, 2001, we also published an interim final rule with comment period (66 FR 55850) that set forth the criteria the Secretary will use to establish new categories of medical devices eligible for transitional pass-through payments under Medicare's OPPS.

- On November 30, 2001, we published a final rule

(66 FR 59856) that revised the Medicare OPPS to implement applicable statutory requirements, including relevant provisions of BIPA, and changes resulting from continuing experience with this system. In addition, it described the CY 2002 payment rates for Medicare hospital outpatient services paid under the PPS. This final rule also announced a uniform reduction of 68.9 percent to be applied to each of the transitional pass-through payments for certain categories of medical devices and drugs and biologicals.

- On December 31, 2001, we published a final rule (66 FR 67494) that delayed, until no later than April 1, 2002, the effective date of CY 2002 payment rates and the uniform reduction of transitional pass-through payments that were announced in the November 30, 2001 final rule. In addition, this final rule indefinitely delayed certain related regulatory provisions.

- On March 1, 2002, we published a final rule (67 FR 9556) that corrected technical errors that affected the amounts and factors used to determine the payment rates for services paid under the Medicare OPPS and corrected the uniform reduction to be applied to transitional pass-through payments for CY 2002 as published in the November 30, 2001 final rule. These corrections and the regulatory

provisions that had been delayed became effective on April 1, 2002.

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 Payment Suspensions for Unfiled Cost Reports

This provision is set forth in our existing regulations at 42 CFR 405.371 as follows:

Section 405.371 (a) provides that Medicare payments may be suspended, in whole or in part, following overpayments determined by the Medicare contractor when overpayment exists or when the payments to be made may not be correct.

Section 405.371(b) provides, in relevant part, that a payment suspension may proceed only after certain procedural requirements contained at §405.372 are met.

Existing §405.371(c) provides for suspension of payment if a provider has failed to timely file an

acceptable cost report. Payment to the provider is immediately suspended until a cost report is filed and determined by the intermediary to be acceptable.

With the increased transition to the prospective payment systems, the cost report settlement process has become less determinative of an institutional provider's Medicare reimbursement. For instance, in the case of an inpatient acute care hospital, the base DRG payment (as opposed to any teaching or disproportionate share payments, or pass-through payments) is determined when a claim is initially adjudicated, and does not generally change at the time of cost report settlement. Similarly, the APC payment for an outpatient service is also based on the claim adjudication. For home health agencies, minimal changes to payment are made at the time of cost report settlement, and for skilled nursing facilities, the main cost report issues revolve around bad debt determinations. In all of these cases, a significant proportion of the institution's payments are determined based on the adjudication of claims, and do not change at the point of settling the cost report. However, the filing of cost reports remains important for settling some payments, such as medical education payments, even for providers that are fully transitioned to prospective payment systems. Also, cost

reports for PPS providers are used for determining prospective payment rates for future years. For these reasons, tailored payment suspensions can still be an effective measure for ensuring that providers comply with their obligation to file timely and acceptable cost reports.

II. Proposed Changes to the Ambulatory Payment

Classification (APC) Groups and Relative Weights

Under the OPSS, 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 OPSS 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 or mean 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."

The APC groups that we are proposing in this rule as the basis for payment in 2003 under the OPPS have been analyzed 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 OPFS.

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 website. We convened the second meeting of the Panel on January 22 through January 24, 2002.

2. General Issues Considered by the Advisory Panel

In this section, we summarize 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 OPPTS payment issues.

Content for Future Presentations to the Panel

During the 2001 meeting, the Panel heard many different types of oral presentations. 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, during the 2001 meeting, the Panel recommended the creation of a Research Subcommittee. The Research Subcommittee was established during the 2001 meeting and had regular conference calls to discuss the development and implementation of standards for written submissions and oral presentations to the Panel during its meetings. The Research Subcommittee also analyzed complex issues (such as the use of multiple procedure claims data to set APC

relative weights) that could not be addressed in the time allotted for the annual 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
32201	Drain, percut, lung lesion
33967	Insert ia percut 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

The Panel recommended that we solicit comments and additional information from hospitals and medical specialty societies that have an interest in these procedures. The Panel also recommended that we present to them at their 2003 meeting 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. Panel members stated that this add-on code is being billed with surgical procedures that are payable under the OPPS. The Panel noted that coding edits prevent payment for the other payable OPPS services if CPT code 47001 is on the claim. We agree with the Panel's recommendation and we propose to remove 47001 from the inpatient list. We further propose to assign it status indicator "N" so that costs associated with CPT code 47001 would be packaged into the APC payment for the primary procedure performed during the same operative session.

One presenter at the Panel meeting suggested removing CPT codes 53448, 54411, and 54417 from the inpatient list because he believed they were being performed in the outpatient setting. After discussing this suggestion, the Panel recommended that these codes remain on the inpatient list because they involve removing a prosthesis through an infected operative field and cannot be safely and effectively performed in the outpatient setting. We agree

with the Panel's recommendation, and we are not proposing to remove these codes from the inpatient list.

In section II.B.5 of this preamble, below, we discuss additional procedures, which were not considered by the Panel, that we propose to remove from the inpatient list. We discuss in detail our reasons for proposing these additional changes, and we propose 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 lists all the procedures we propose to remove from the inpatient list, including those discussed by the Panel. We are considering 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 have not been able to confirm that this procedure is being performed on Medicare beneficiaries in an outpatient setting. We solicit comments, including clinical data and specific case reports, that would support payment for CPT 33967 under the OPPS.

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. This code family was selected because presenters had suggested that when procedures in this family are performed, it is typical to perform more than one procedure during a session.

The Subcommittee reviewed pre-OPPS claims data for these codes, paying particular attention to common code combinations and costs per procedure and per code combination. After lengthy review, the Panel concluded that (1) it could not determine whether findings based on review of pre-OPPS data could be extrapolated to post-OPPS claims data; (2) the variability in allocation of costs across ERCP line items and the existence of claims where the same ERCP code was billed more than once indicate that problems exist with the accuracy of facility coding for these procedures; and (3) analysis of multiple claims data for ERCP may not be applicable to other sets of services.

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 agree. We describe in section II.B.4 how we determined the number of single claims used to set the APC relative weights proposed for 2003 using this methodology. We ask for comments on our methodology.

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.

There are a number of reasons why we package the costs of certain procedures. For example, “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 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.

Several presenters to the panel requested that we not package any radiologic guidance or supervision and interpretation codes. They believe that hospitals will not use codes for which they do not receive a separate payment. If that were the case, it would be difficult to track utilization for these procedures and make it difficult for radiology departments to receive an appropriate payment for their services. A few presenters also pointed out that various forms of guidance with widely varying costs can be used for a single surgical procedure. Therefore, we might unintentionally create an incentive for inappropriate care

by packaging several guidance procedures with varying costs into a single surgical code. Additionally, a manufacturer of ultrasound guidance equipment used for placement of radiation fields commented that, because guidance is rarely used for this purpose, its costs could not be adequately captured by packaging it into a common procedure where the vast majority of claims did not use guidance.

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.

Add-On Codes

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. Add-on codes described additional

procedures performed by the same physician that are associated with the primary procedure, and which cannot be billed without the primary procedure. Such a methodology would create a single, weight averaged payment for the parent procedure and the add-on procedure while addressing the problem that any "single" claim for an add-on procedure is, by definition, an error claim. 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 propose 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 are proposing 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 this section, we consider the Panel's recommendations affecting specific APCs. 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. 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 Addenda 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.

A presenter to the Panel who represented a device manufacturer noted that the resources used to provide 95921, Autonomic nerve function test, are not similar to the resources required for performing the procedures in APC 218, where we had suggested moving the device. He requested that the code be reassigned to APC 216 where it resided in calendar year 2000. Because there were very few claims for the code in the 1999 and 2000 data, the Panel voiced concern about making the change without sufficient data to support such a move.

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

The Panel's recommendations related to facility coding for clinic and emergency department visits are discussed below, in section VIII.A.

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.

One presenter to the panel objected to the use of miscellaneous APCs in the OPPS. The presenter argued that we are charged with creating clinically coherent APCs and that miscellaneous APCs contradict the principle of clinical coherence. We noted that in spite of considerable effort to do so, we have not been able to incorporate the procedures assigned to miscellaneous APCs into other, more clinically homogeneous APCs. We asked the presenter to propose a configuration for consideration.

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 propose further changes for the Panel's consideration next year.

We propose 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 propose to accept the Panel's recommendations. We note 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 propose to accept the Panel's recommendations because they result in more clinically coherent APCs. We solicit comments on further changes that would address the violations of the 2 times rule. We plan to place these APCs on the panel's agenda for 2003.

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 was inaccurate. These APCs were on the agenda this year in order to obtain further comment on our cost data. We suggested no changes in the structure of these APCs.

Representatives of two associations made presentations regarding these APCs. One recommended that all the plasma derivatives and recombinant analogs that currently receive transitional pass-through payments be assigned to permanent

APCs in 2003, similar to the designations of other blood products. The representative of the second association supported this recommendation.

The second presenter also pointed out that, consistent with our billing instructions, every claim that a hospital submits for a blood transfusion should include codes for both the blood product and the transfusion. Therefore, payment for blood and blood products is another area affected by the use of single bills in setting payment weights. The Panel agreed to look specifically at blood in its work on the multiple claims issues.

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 III.C, we discuss 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 propose not to accept the Panel's recommendation to change current OPSS payment policy for transfusions. The current payment

reflects weight averaging over the number of units transfused. Therefore, unless a hospital specializes in transfusing multiple units of blood, payments for this procedure should be, on average, appropriate.

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 OPSS 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 propose 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 propose 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 OPSS cost data shows continuing violations of the 2 times rule and that costs within these APCs are virtually identical. Therefore, we propose 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 agree 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 propose 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 propose 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 propose 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 propose 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 propose to move the procedures in APCs 144 and

145 to APC 147 with the exception of CPT code 46600, Anoscopy; diagnostic, which we propose 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 propose to move CPT codes 92543, 92588, 92520, 92546, 92516, 92548, and 92584 to new APC 0660 (Level III Otorhinolaryngologic 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. Several groups made a joint proposal to reconfigure these APCs arguing that their proposal resulted in more clinically coherent APCs. However, several other presenters commented that the joint proposal did not include several physician groups who commonly perform these procedures.

Based on 2001 claims data, we propose to make several changes in order to resolve 2 times rule violations and to make these APCs more clinically coherent. Specifically, we propose 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 propose to move CPT codes 78627, 76825, and 93320 from APC 0269 to new APC 0671 to achieve more clinical coherence. We also propose 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 propose 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 solicit 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

APC 694: Level III Excision/Biopsy

Based on 2001 claims data, we propose to move several codes from APC 19 to APC 20 and several codes from ACP 20 to APC 21. Additionally, we propose to move CPT codes 11770, 54105, and 60512 to APC 22. We also propose 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 propose 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 propose 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 codes moving from APC 26 to APC 25 or APC 27.

Table 1: HCPCS Codes Proposed 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
14020		14020
14021		14021
14040		14040

2002 APC 26	2003 APC 25	2003 APC 27
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

2002 APC 26	2003 APC 25	2003 APC 27
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 propose 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.

B. Other Changes Affecting the APCs

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 proposed 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 the APCs to determine which of them would not meet the 2 times limit. We use the following criteria

when deciding whether to make exceptions to the 2 times rule for affected APCs:

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

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

The following table contains APCs that we propose to exempt from the 2 times rule based on the criteria cited above. In cases in which 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 website:

<http://www.cms.hhs.gov>.

Table 2 - Table of Exempted Codes

NPRM 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
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

NPRM APC	Description
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
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 propose to move several procedures from new technology APCs to clinical APCs. Those procedures and the clinical APCs to which we propose to assign the procedures for payment in 2003 are identified in Table 3. Based upon our review of the 2001 OPPS claims data, we believe 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. We compared median cost data for the new technology procedures with median cost data for procedures that are clinically similar and for which we

would expect costs to be similar. We also compared median cost data for the new technology procedures with median cost data for clinically related procedures, such as different methods of treating prostatic hypertrophy, where expected median costs were lower or higher than those of the new technology procedure. In some cases we propose 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 propose 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 solicit comments on our proposed reassignment of the new technology procedures listed in Table 3.

Table 3: Proposed 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 percut 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
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

HCPCS	Description	2002 SI	2003 SI	2002 APC	2003 APC
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	Diagnosticmammographydigital	S	S	0707	0669
G0206	Diagnosticmammographydigital	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 2002

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, the assignments are open to public comment in this proposed rule. In this proposed

rule, we solicit comment on the APC assignment of these services. In addition, in this proposed rule, we are proposing the creation of several new HCPCS codes and APC assignments with an effective date of January 1, 2003.

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 propose to implement 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. Furthermore, neither the new procedural HCPCS nor the new pass-through codes intended as of this publication for implementation beginning October 2002 or later are included in Addendum B of this proposed rule.

Table 4 - New G Codes for 2002 and Proposed G Codes for 2003

Code	Long Descriptor	APC	SI	Proposed Effective Date
G0245	Initial physician evaluation of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include the procedure used to diagnose LOPS; a patient history; and a physician examination that consists of at least the following elements-...	0600	V	7/01/02

Code	Long Descriptor	APC	SI	Proposed Effective Date
G0246	Follow-up physician evaluation of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include the procedure used to diagnose LOPS; a patient history; and a physician examination that includes-...	0600	V	7/01/02
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-...	0009	T	7/01/02
G0248	Demonstration, at initial use, of home INR monitoring for a patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstration 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 a patient's ability to perform testing	0708	S	7/01/02
G0249	Provision of test material 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	0708	S	7/01/02
G0250	Physician review/interpretation and patient management of home INR test for patient with mechanical heart valve(s) who meets other coverage criteria; per 4 tests (does not require face-to-face service)	N/A	E	7/01/02
G0AAA	PET imaging for initial diagnosis of breast cancer and/or surgical planning for breast cancer (for example, initial staging of axillary lymph nodes), not covered by Medicare.	N/A	E	10/01/02
G0BBB	PET imaging for breast cancer, full and partial-ring PET scanners only, staging/restaging after or prior to course of treatment	0285	S	10/01/02
G0CCC	PET imaging for breast cancer, full and partial-ring PET scanners only, evaluation of response to treatment, performed during course of treatment	0285	S	10/01/02
G0DDD	Current Perception Threshold/Sensory Nerve Conduction Test, (SNCT) per limb, any nerve.	N/A	E	10/01/02
G0EEE	Intravenous infusion(s) during separately payable observation stay, Per observation stay (must be reported with G0244)	0340	X	10/01/02
G0FFF	Bone marrow aspiration and biopsy performed through a single incision during a single session	0003	T	1/01/03
G0GGG	Unscheduled or emergency treatment for dialysis for ESRD patient in the outpatient department of a hospital that does not have a certified ESRD facility	0170	S	1/01/03
G0HHH	Injection procedure for sacroiliac joint; arthrography	N/A	N	1/01/03
G0JJJ	Injection procedure for sacroiliac joint; provision of anesthetic, steroid, and/or other therapeutic agent	0204	T	1/01/03
G0KKK	Prostate brachytherapy, including transperineal placement of needles or catheters into the prostate, cystoscopy, and interstitial radiation source application.	0684	T	1/01/03
G0LLL	Initial nursing assessment of patient directly admitted to observation with diagnosis of congestive health failure,	N	N	1/01/03

Code	Long Descriptor	APC	SI	Proposed Effective Date
	chest pain or asthma.			
G0MMM	Initial nursing assessment of patient directly admitted to observation with diagnosis other than congestive heart failure, chest pain or asthma.	0706	S	1/01/03
G0NNN	Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel.	0656	T	01/01/03
G0000	Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel.	0656	T	01/01/03

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 G0AAA-G0DDD will be established October 1, 2002 as a result of national coverage policies that will be effective October 1, 2002. These codes were created to accurately describe the services covered, to ensure they were reported correctly, to track their utilization, and to establish payment. We solicit 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 OPFS.

We expect to implement HCPCS code G0EEE (Intravenous Infusion(s) During Separately Payable Observation Stay) effective October 1, 2002 to describe infusion therapy given during a separately payable observation stay. This code is discussed in detail in section VIII.B of this proposed rule. We have assigned it to APC 0340. We believe APC 0340 appropriately accounts for the resources used for infusion during observation. This is because we believe that Q0081, which represents the same service as G0EEE, is typically billed with an APC that has a higher relative weight, therefore making APC 0120 payable at 50 percent of its payment rate.

HCPCS Codes Proposed in This Rule for January 1, 2003

We are proposing the creation of several new HCPCS codes for 2003 in order to address issues that have come to our attention, to describe new technology procedures, to implement policy proposals discussed in this rule, and to allow more appropriate reporting of procedures currently described by CPT (HCPCS Level I) codes.

- (1) G0FFF - Bone Marrow Aspiration and Biopsy Services - we are proposing to create this code to describe bone marrow aspiration and biopsy performed through the same incision. We propose 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.

- (2) G0GGG - Unscheduled and Emergency Treatment for ESRD Patients - we are proposing this code in order to facilitate payment for dialysis provided to ESRD patients in the outpatient department of a hospital that does not have a certified ESRD facility. This code is described in detail in section VIII.G of this proposed rule.
- (3) G0HHH and G0JJJ - Sacroiliac Joint Injections - we are proposing 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 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 propose to

create G0HHH, Injection procedure for sacroiliac joint, arthrography, and G0JJJ, Injection procedure for sacroiliac joint, provision of anesthetic and/or steroid. G0HHH would be given status indicator N, and G0JJJ would be assigned to APC 0204.

- (4) G0KKK - Prostate Brachytherapy - we are proposing this code to implement our policy decision discussed in section III.C.3 of this proposed rule.
- (5) G0LLL and G0MMM - Observation Care - we are proposing 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. These codes are discussed in detail in section VIII.B of this rule.
- (6) G0NNN, G0000; Drug Eluting Stents -

Drug-Eluting Stents

Drug-eluting coronary artery stents (referred to as "drug-eluting stents" in the discussion that follows) have been developed to combat the problem of restenosis of blood vessels previously treated for stenosis. The drug is coated on a stent with a special polymer, and after the stent is placed in the vessel, the drug is slowly released into the vessel wall tissue over a period of 30 to 45 days. The drug coating on the stent is intended to prevent the

build-up of scar tissue that can narrow the reopened artery. The FDA has not yet approved this technology for general use. We understand the earliest date that a decision from the FDA is anticipated is late 2002.

We received an application to establish a new medical device category eligible for transitional pass-through payment under the OPPTS for drug-eluting stents from a manufacturer of these stents. In the application for the new device category, the manufacturer asserts that drug-eluting stents meet the criteria for establishing a new device category that were set forth in the November 2, 2001 Federal Register. Specifically, the manufacturer believes a new device category is appropriate because drug-eluting stents meet the cost significance thresholds for a new device category, and they provide substantial therapeutic benefit to Medicare beneficiaries compared to other available therapies for coronary atherosclerosis.

Based on our review of the application as well as other information pertaining to drug-eluting stents, we determined that drug-eluting stents are described by an existing pass-through device category. As we discuss in section III.D of this preamble, section 1833(t)(6)(B)(ii)(IV) of the Act requires that a new category must include medical devices for which no existing

category, or one previously in effect, is appropriate. In the program memorandum that we issued to our contractors on March 22, 2001 (Transmittal A-01-41) with instructions for the implementation of category codes for use in making transitional pass-through payments for devices, we established two categories that describe and could be used to bill for drug-eluting stents: HCPCS code C1874, Stent, coated/covered, with delivery system, and HCPCS code C1875, Stent, coated/covered, without delivery system. These two categories were based on devices that previously qualified for transitional pass-through payment on an item-specific basis. Although these two device categories are among those that will sunset after December 31, 2002, as we discuss in section III.C of this preamble, the fact that they exist precludes the establishment of a new device category for drug-eluting stents.

Payment for drug-eluting stents is not allowed under the OPPI until they receive FDA approval for general use. If the drug-eluting stents are approved for general use by the FDA, payment would be packaged into the APC payment for the procedures with which the stents are used. The cost of drug-eluting stents would be incorporated within the APC relative payment weights when we recalibrate the payment weights in CY 2005 using CY 2003 claims data.

In considering how we would pay for drug eluting stents under OPPTS we thought carefully about how the payment should relate to payment for these stents under IPPS. Section 533 of BIPA added sections 1886(d)(5)(K) and (d)(5)(L) to the Act (as implemented by §§42 CFR 412.87 and 412.88) to reduce the time needed under the hospital inpatient PPS for the DRG system to recognize the higher costs of new technologies that meet certain criteria. Drug-eluting stents did not meet the inpatient PPS new technology cost threshold criterion in the May 9, 2002 proposed rule to update the hospital inpatient PPS for FY 2003. Therefore, in that proposed rule, we listed a new ICD-9 procedure code 36.07 (Insertion of drug-eluting coronary artery stent(s)) that would be effective for use October 1, 2002. We also proposed to add ICD-9 code 00.55 (Insertion of drug-eluting noncoronary artery stent) (67 FR 31630). To be consistent with our prior practice of assigning new technology to the same DRGs to which its predecessor technologies were assigned, we proposed in the May 9 inpatient PPS proposed rule to assign inpatient cases involving ICD-9 code 36.07 to DRG 517 (Percutaneous Cardiovascular Procedure with Coronary Artery Stent without AMI).

However, comments to the May 9, 2002 proposed IPPS rule and our own further consideration of this issue persuaded us that a different approach was needed for the IPPS given the preliminary evidence that drug-eluting stents could prove potentially to be transformational technology in the treatment of coronary artery disease. While this technology is not yet approved for general use by FDA, commenters to the May 9 hospital inpatient PPS proposed rule reported that drug-eluting stents have shown promise to significantly advance the treatment of coronary artery disease, and they encouraged CMS to consider the available data to determine the most appropriate DRG payment. Commenters supported reassignment of the new procedure codes for drug-eluting stent insertions to higher paying DRGs or, if necessary, the modification of all affected DRGs, once verifiable data on the costs associated with drug-eluting stents become available.

Many of the commenters who supported higher payment under the inpatient PPS for this technology were clinical practitioners and hospitals, who expressed great anticipation for the potential benefits of this technology. In addition, commenters referred to the likelihood that, once approved, patients would demand to have these new

drug-eluting stents, putting tremendous financial strain on hospitals.

Commenters to the proposed rule for the inpatient PPS for FY 2003 also argued there should be long-term cost savings to the Medicare program and the health system generally from this technology after approval by the FDA. Specifically, if dramatically fewer patients require restenting, savings will result from fewer repeat angioplasty procedures. And, to the extent bypass surgeries are reduced, savings would result from that outcome as well.

In responding to these commenters in the inpatient final rule published in the Federal Register on August 1, 2002 (67 FR 50003), we noted that, although the FDA has not yet approved this technology for general use, public presentation of the results from recent clinical trials have found virtually no in-stent restenosis in patients treated with the drug-eluting stent. Therefore, we recognize the potentially significant impact this technology may conceivably have on the treatment of coronary artery blockages.

We are concerned that, if the FDA does approve this technology and the predictions of its rapid, widespread use are accurate, significant strain on hospital financial

resources would result. In particular, we are concerned that the higher costs of this technology would create undue financial hardships for hospitals due to the high volume of stent cases and the fact that a large proportion of these cases could involve the new technology soon after FDA approval. Therefore, in the final rule for the FY 2003 inpatient PPS, we implemented an unprecedented approach in response to the unique circumstances surrounding the potential breakthrough nature of this technology and we created two new DRGs to reflect cases involving the insertion of a drug-eluting coronary artery stent. We discuss in detail in the final inpatient PPS rule our rationale for establishing these DRGs (67 FR 50003-50005).

Although the clinical trials for drug-eluting stents are being conducted on hospital inpatients, our 2001 hospital outpatient claims data included nearly 18,000 claims for procedures utilizing other types of coronary stents in the hospital outpatient setting. Every indication points to a steady increase in the future volume of coronary stent procedures performed on an outpatient basis. The same concerns that we express above about the impact of the advent of drug-eluting stents on hospital resources apply to procedures performed in the outpatient setting as well as the inpatient setting. We created these

new DRGs for drug-eluting stents to ensure and promote beneficiary access to the best care possible by ensuring that our payment system keeps pace with what we believe will be a growing volume of coronary stent procedures if FDA approves drug-eluting coronary artery stents. We want to ensure that the costs of drug-eluting stents will be recognized sufficiently quickly to ensure beneficiary access in the outpatient setting over the 2 years that it will take for the costs of these devices to appear in the Medicare data on which we will base Medicare payments for them.

Drug-eluting stents may have been commercially marketed for 2 years by the time cost data for stent insertion procedures performed in CY 2003 are incorporated into the APC relative weights under the OPPS for CY 2005. Therefore, as we have done under the inpatient PPS for FY 2003 under these exceptional circumstances, we propose to deviate from our standard OPPS payment methodology 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 propose 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 OPSS, 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 illness or injury as determined by Medicare contractors based on the specifics of individual cases.

The new HCPCS codes that we propose are as follows:

G0NNN - Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; single vessel

G0000 - Transcatheter placement of a drug eluting intracoronary stent(s), percutaneous, with or without other therapeutic intervention, any method; each additional vessel

We propose to assign G0NNN and G0000 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 propose to apply the same assumptions that we used in establishing the weights for 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, based on prices in countries where drug-eluting stents are currently being used, manufacturer information and information furnished in response to the May 9, 2002 IPPS proposed rule, and the average price of currently available stents, we assume a price differential of approximately \$1,200. Using an average of 1.5 stents per procedure, we propose to add \$1,200 to the median costs established for APC 0104 based on 2001 claims data. We would then calculate a relative payment weight and payment rate for APC 0656 in accordance with the methodology that we discuss in section II.B. of this preamble. By taking this approach, we believe that payment for drug-eluting stents would be balanced between the OPSS and the inpatient PPS, minimizing the incentive to use payment as the basis for determining where to furnish this new technology.

We are taking the extraordinary temporary measure of establishing this APC and pricing it as we propose only

because we have been advised by experts that these stents can be expected to revolutionize the provision of coronary care and can be expected to supplant use of existing stents. While the statute contemplates the difficulties of setting OPPS payments for new devices by providing the transitional pass-through mechanism, that mechanism does not work in this circumstance since these devices fall into a previously existing device category and do not meet the test for inclusion in new technology APCs. However, the law permits us to take into account changes in technology and the addition of new factors (See section 1833(t)(9)(A)) of the Act. In this case, we think the impact of this new technology will be so great compared to other new technologies that, to ensure beneficiary access to state-of-the-art medical care, we believe that we need to create new codes and a separate APC, paid based on the best information currently available, to ensure adequate payment to providers and access to care during the first 2 years of the device's existence. To undertake this methodology in other cases, we would have to be similarly convinced that the technology would not qualify for pass-through payment nor new technology APC payment, that it will revolutionize the provision of care and that it will replace an existing technology. As indicated previously, this payment

mechanism would be a temporary one that would exist only until 2005, at which point we would have sufficient data to determine how to pay for these devices under the standard OPSS methodology for setting payment amounts.

We propose to implement payment under APC 0656 effective April 1, 2003, consistent with the effective date for implementation of the drug-eluting DRGs under the OPSS 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.

We are proposing 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. Once we obtain adequate cost data for coronary artery drug-eluting stents, we propose to incorporate these data into the current CPT codes for coronary stent placement. We invite comments on this proposed methodology for recognizing the additional costs of drug-eluting stents under the OPSS.

It is important to emphasize that we anticipate that the vast majority of new technologies in the future will continue to be routinely incorporated into the existing DRGs or through the new technology add-on payments under

the inpatient PPS. Similarly, we expect in the future to continue to make payment under the OPPS for the vast majority of new technologies through the existing provisions for transitional pass-through payments for new devices, drugs, and biologicals and through new technology APCs.

4. 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 are proposing to use the same basic methodology that we described in the April 7, 2000 final rule. That is, we would recalibrate the weights based on claims and cost report data for outpatient services. We

propose to use the most recent available data to construct the database for calculating APC group weights. For the purpose of recalibrating APC relative weights for 2003, the most recent available claims data are the approximately 110 million final action claims for hospital outpatient department services furnished on or after January 1, 2001 and before January 1, 2002 and processed through March 2002. Many of these 110 million claims 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

We have received many requests (through an April Town Hall meeting and other sources of contact with the public) asking that we ensure that the data from claims that contain charges for multiple procedures are included in the data from which we calculate the 2003 relative payment weights. They believe that relying solely on single procedure claims to recalibrate APC weights fails to take into account data for many frequently performed procedures,

particularly those commonly performed in combination with other procedures.

We agree that optimally, it is desirable to use the data from as many claims as possible to recalibrate the relative payment weights, including those with multiple procedures. We identified certain multiple procedure claims that could be treated as single procedure claims, enabling us to greatly increase the number of services used to develop the APC payment weights for 2003. However, several inherent features of multiple bill claims prevented us from using all of them to recalibrate the payment weights. We discuss these obstacles below.

There are four scenarios that occur when multiple procedures are billed on a claim that result in our being unable to use all of those claims to recalibrate the APC weights. In each case, the underlying problem is that there are charges on the claim that we are unable to correctly associate with the HCPCS codes for the procedures on the claim (that is, payable HCPCS codes). In general, we are unable to determine with confidence what portion of those charges should be packaged into the charges for each of the procedures on the claim. The different scenarios that we describe below may occur singly or in combination on the same claim.

In the first scenario, costs associated with outpatient hospital services are reported in revenue centers that cannot be associated with individual HCPCS codes because they are ancillary and supportive of some or all services furnished to the beneficiary. We do not require that hospitals assign a HCPCS code to each revenue center and charge or that they split the charges within revenue centers by HCPCS code because they advise us that they are unable to account for costs in this manner. In addition, to collect and report this information would be burdensome and costly.

Where there is only one HCPCS code for a procedure on the claim, we can assign supporting charges in revenue centers to the single HCPCS code. However, when there are two or more HCPCS codes for procedures on the claim, we have no basis for allocating appropriately the ancillary charges reported under revenue centers to the HCPCS codes for separately payable procedures. For example, a claim containing HCPCS codes for a visit and a surgical procedure may show charges under the revenue center for family clinic (517) for the visit and under operating room (360) for the surgery. But in addition, the claim could show charges under the following revenue centers without assigning a HCPCS code to the revenue center: recovery room (710),

charge A for sterile supplies (272), charge B for sterile supplies (272), anesthesia (370), and pharmacy (250). If only a single HCPCS code was billed, we could sum the charges shown under the ancillary revenue centers and attribute those charges to the HCPCS code for the single HCPCS code that was billed. However, because there is more than one separately payable code on the claim (clinic visit and surgery), we do not know which charge for sterile supplies should be mapped to the visit and which should be assigned to the surgery. Similarly, there is nothing on the claim to indicate whether the total pharmacy charge is associated with the surgery or with the clinic visit, or split between them. For this type of multiple procedure claim, we have chosen to exclude the claim from the pool of charges used to calculate median APC costs rather than risk assigning the ancillary revenue center charges incorrectly. This type of multiple procedure claim, often much more complex than this example, accounts for a significant portion of the multiple procedure claims that we are unable to use to recalibrate payment weights.

In the second scenario, we are unable to correctly assign to procedures the charges for HCPCS codes that we package into other procedures. HCPCS codes with status indicator "N" are not paid separately. Rather, the payment

for these packaged items or services is recognized in the payment for a service or services billed on the same claim for which there is an APC payment rate. In calculating the median costs, we have to know where to incorporate the charges shown for the HCPCS code with status indicator "N." When a packaged HCPCS code is on a claim that also bills for more than one primary procedure (that is, procedures for which we make separate payment), we do not know with which of the procedures the charges for the packaged HCPCS code should be associated, or whether the charges for the packaged HCPCS code should be apportioned on some basis among the multiple primary procedures.

In the third scenario, in the case of multiple surgical procedures, our billing instructions permit hospitals to show charges for only one surgical procedure code although they report more than one surgical HCPCS code. Specifically, this billing convention has long been permitted in Medicare Intermediary Manual section 3626.4B3 and was reconfirmed by Medicare Transmittal A-01-50, which was issued on April 12, 2001

(<http://www.hcfa.gov/pubforms/transmit/A0150.pdf>) in response to hospital requests that we clarify whether they were required to create and report charges for each HCPCS code for each surgical service billed on a claim. We

believe that to report charges for each HCPCS code for surgical services would have imposed an additional accounting and billing burden on hospitals that had not previously existed. This would have been in addition to the changes to the claims format and instructions that hospitals had recently made to accommodate OPPS and our other initiatives. As in the case of the ancillary services billed under revenue centers, the charges for each HCPCS code for the surgery were not needed to ensure that correct payment was made on the claim (since payment was made based on the code's APC assignment and not on reported charges).

However, because hospitals are permitted to report operating room charges for only one of the multiple surgical procedures on a claim, we are unable to identify a valid means of apportioning the operating room charges to the other procedures that were performed. We are not aware of any research on comparative hospital outpatient department (OPD) resource consumption by HCPCS codes that would indicate how to apportion a total charge among the individual codes on the claim. Moreover, these multiple surgical procedure claims frequently have problems similar to those discussed above in scenario one. Therefore, we

are unable to use data from multiple surgery claims that are submitted in this form to calculate APC median costs.

In the fourth scenario are claims with multiple units of the same HCPCS code billed with charges in revenue centers or packaged HCPCS codes. In this case, we cannot determine the appropriate distribution of charges on the claim between the first and subsequent units of the HCPCS code. To approximate the charges that would occur if single rather than multiple units of the HCPCS code were billed, we would have to inflate the charges for the second and subsequent units of the service, which would eliminate the impact of the efficiencies that we believe occur when second and subsequent units of a procedure are performed. There are no data to suggest an appropriate factor to apportion charges for the second and subsequent units.

We considered several methods of apportioning charges from revenue centers and packaged HCPCS codes to enable us to use charge data from multiple procedure claims in the calculation of APC weights, but none of these methods was sufficient to yield cost data that we could be assured were valid. Specifically, we considered dividing the total charges in a revenue center or for a packaged HCPCS code by the number of payable HCPCS codes for multiple procedures on the claim. In the example of a claim for a visit code

and a surgical code with the revenue center for sterile supplies billed twice on the same claim, we would sum the charges for sterile supplies, divide the sum by 2, and add the resulting divided charges for sterile supplies to the charges for each HCPCS code. The single pharmacy charge would be divided by 2, and half of the pharmacy charge would be added to each HCPCS code. We rejected this approach because of concern about whether it is likely to be sufficiently accurate to serve as a reasonable means of apportioning charges.

We also considered apportioning the charges among the codes based on physician work relative value units (RVUs) because time is a major factor in the establishment of physician work RVUs under the Medicare fee schedule for physician services. Time may be reflective of the comparative amount of resources used by the hospital for different surgical procedures, particularly charges for operating rooms, recovery rooms, and observation rooms. However, physician work RVUs also depend in part on the intensity and difficulty of the work of a physician in providing a service and would therefore not necessarily reflect accurately the relative resources a hospital would expend for the same procedure. Moreover, we do not believe

that time appropriately reflects the use of resources such as pharmacy and supplies.

We then considered apportioning the charges among the codes based on physician nonfacility practice expense RVUs because practice expense RVUs reflect relative resource utilization for these services. However, we have no evidence that the relative practice expenses of physicians correlate with the resources that a hospital would use for the same service. Moreover, physician practice expenses are minimal for the many services typically furnished in a facility rather than the physician's office. For these services, the practice expense RVU reflects only minimal expenses for services, such as the physician's billing costs. They are, therefore, an inadequate proxy for the facility costs, such as supplies, drugs, equipment, nursing services, and overhead costs incurred by hospitals.

In summary, we concluded that the inherent drawbacks of these methodologies would outweigh any potential advantages accrued from the resulting increase in data used to calculate APC median costs. Without evidence to the contrary, we believe that applying these arbitrary methods of apportioning costs to multiple procedure claims would yield results that are less reliable and valid than

continuing to rely on single procedure claims in calculating APC median costs.

We solicit public comment on the methods we considered for apportioning the total charges to individual HCPCS codes as described above. We also invite 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 OPDS.

We also solicit information on existing studies that would provide comparative hospital outpatient resource inputs by HCPCS code. In addition, we welcome 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.

Further, we ask for comments on the feasibility of requiring hospitals 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 the relative weights. For example, where the patient received multiple surgeries on the same day or received a visit and a procedure on the same day, the

hospital would have to create a charge for each billable HCPCS code and that charge would have to encompass all charges for OR, recovery room, pharmacy, supplies, etc. that were relevant to that code. No charges would be billed under revenue centers alone or with packaged HCPCS codes (that is, HCPCS codes having a status indicator of N) since all charges would be reported under associated payable HCPCS codes. There would have to be corollary changes in completion of the cost report. Also, because hospitals must have a uniform charge structure, providers would need to charge all other payers and private pay patients in the same manner as they would be required to charge Medicare.

We are particularly interested in the views of hospitals and billing experts weighing the burden that could be created by these changes in billing rules relative to the potential benefit of calculating more precise OPPS payment rates that incorporate data from multiple procedure claims.

Finally, we solicit information regarding the extent to which efficiencies are realized when multiple services are furnished during the same visit or operative session. We currently discount the APC payment for the second and subsequent procedures performed during a single encounter

by 50 percent in the expectation that the same efficiencies of service that are demonstrated to exist in the provision of physician services also exist in the provision of outpatient hospital services. In general, when a second or subsequent service is performed at the same time as an initial service, we believe that the combined resource costs associated with operating room time, recovery room time, anesthesia, supplies, and other services are less than if the procedures were performed separately. However, we are interested in empirical data regarding the extent to which these efficiencies of resource consumption actually occur.

(2) Calendar Year 2002 Charge Data for Pass-Through Device Categories

HCPCS coding for medical devices that qualified for transitional pass-through payment for services furnished in 2001 occurred in two different ways. (A detailed discussion of the provisions authorizing transitional pass-through payments for certain medical devices and drugs and biologicals can be found in section III of this preamble.) From August 1, 2000 until April 1, 2001, claims for medical devices that were paid on a pass-through basis were coded using device specific codes that were often manufacturer specific. BBRA required that, effective April 1, 2001,

claims for medical devices eligible for transitional pass-through payment were to be billed using codes that applied to categories of devices. We issued the applicable category codes in Program Memoranda, Transmittals A-01-40 and A-01-41. We posted them on our web site at <http://www.hcfa.gov/pubforms/transmit/A0140.pdf> and <http://www.hcfa.gov/pubforms/transmit/A0141.pdf>, respectively. The change to the use of category codes, rather than device specific codes, simplified coding and also expanded the number of devices that were eligible for transitional pass-through payment. The expansion occurred because devices that fit the categories but that had previously not met the criteria for transitional pass-through payments could now be billed for a transitional pass-through payment.

Moreover, in recognition of the impact of the change on hospital billing and in recognition of the short time between the passage of legislation (December 14, 2000) and the effective date for the new codes (April 1, 2001), we gave hospitals a 90-day grace period during which they could bill using either the device specific codes they had previously been using or the new category codes. For this reason, only services furnished on or after July 1, 2001

were required to be billed using the new device category codes.

We have 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 understand that the changes in billing format and systems for implementation of the OPPS compounded the problems of billing using the device specific codes during the first 9 months of the OPPS. We have 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 have 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 agree that where hospitals failed to show the code for the transitional pass-through device (whether the device specific code or the category code as applicable), they will not have received payment for the device as a transitional pass-through device. For many years, there have been processes in place for hospitals to submit

adjustment bills so they can receive payment for all applicable services they furnished if they subsequently determine that their original bills were deficient. Notwithstanding, there is no method by which we can infer a charge on a claim for a service that is not billed by the hospital.

Regarding the impact of the absence of coding for devices on the data from claims submitted for July 2001 and later, we looked at the claims data for a sample of services for which we thought there should have been a device category billed because of the nature of the procedure (for example, insertion of a pacemaker). We found that there were many instances when a device category code was not billed when we would have expected it. However, we found that when we summed the charges for revenue centers with the charges for the procedure on claims where no category code was reported and compared those totals with the sum of charges from claims where both a device category code and the associated procedure code were billed, the results were very similar. From this analysis, we conclude that in many cases, particularly during the first half of the calendar year, hospitals included charges for transitional pass-through devices in the revenue center for supplies. Therefore, we believe

cost data for transitional pass-through devices are contained in the charges of most claims, even where they are not separately identified by the code for the device category, which should have been reported.

We believe that this absence of category codes in the claims data and our data analysis, and the issues surrounding multiple procedure claims argue strongly for packaging the cost of these devices into the payment for the procedures with which they were used and to then create weights for procedures for the 2003 OPPS. Incorrect device coding could lead to skewed weights for the retired transitional pass-through devices, if we were to establish individual APCs for the expired device categories.

We believe that packaging the charges billed under the revenue centers into the charges for the procedures before setting the weights for the APCs will allow us to capture all of the cost data for services in which devices were used which will result in the most valid payment for the APC. This approach assures that the payment rate for the procedure includes accurate payment for the devices used in the procedure. Further discussion of our proposal to package payment for sunseting transitional pass-through devices is contained in section III.C of this preamble.

b. Description of How Weights Were Calculated for 2003

The methodology we followed to calculate the APC relative payment weights proposed for CY 2003 is as follows:

- We excluded from the data approximately 15 million claims for those bill and claim types that would not be paid under the OPPS (for example, bill type 72X for dialysis services for patients with end-stage renal disease (ESRD)).

- 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 that 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 million claims submitted by the hospitals that we removed or trimmed from the hospital CCR data.

- We eliminated 1.2 million claims from hospitals located in Maryland, Guam, and the U. S. Virgin Islands.

- We matched revenue centers from the remaining universe of approximately 92.2 million claims to CCRs hospitals.

- We separated the 92.2 million claims that we had matched with a cost report into the following three distinct groups: (1) single-procedure claims, (2) multiple-procedure claims, and (3) claims on which we could not identify at least one OPPS covered service. Single-procedure claims are those that include only one HCPCS code (other than laboratory and incidentals such as packaged drugs and venipuncture) that could be grouped to an APC. Multiple-procedure claims include more than one HCPCS code that could be mapped to an APC. Dividing the claims in this manner yielded approximately 30.4 million single-procedure claims and 20.1 million multiple-procedure

claims. Approximately 41.5 million claims without at least one covered OPSS service were set aside.

We converted 10.7 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 31.3 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 II.B.4.a.(1) of this preamble, we did not use multiple-procedure claims that billed more than one separately payable HCPCS code with charges for packaged items and services such as anesthesia, recovery room, or supplies that could not be reliably allocated or apportioned among the primary HCPCS codes on the claim. We have not yet developed what we regard as an acceptable method of using multiple-procedure bills to recalibrate APC weights that minimizes the risk of improperly assigning charges to the wrong procedure or visit.

- For each single-procedure claim, we calculated a cost for every billed line item charge by multiplying each revenue center charge by the appropriate hospital-specific CCR. If an appropriate cost center did not exist for a given hospital, we crosswalked the revenue center to a secondary cost center when possible, or used the hospital's

overall 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 5 lists packaged services by revenue center that we are proposing to use to calculate per-service costs for outpatient services furnished in 2003.

Table 5 - Packaged Services by Revenue Code

Revenue Code	Description
<u>SURGERY</u>	
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

Revenue Code	Description
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
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

Revenue Code	Description
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 proposed FY 2003 hospital inpatient prospective payment system (IPPS) wage index published in the **Federal Register** on May 9, 2002

(67 FR 31602). We used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We have used this estimate since the inception of the OPPS and continue to believe that it is appropriate. See 65 FR 18496, the April 7, 2000 final rule 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 3 standard deviations from the geometric mean.

- After trimming the procedure and visit level costs, we mapped each procedure or visit cost to its assigned APC, including, to the extent possible, the proposed APC changes described in section II.A of this preamble.

- We calculated the median cost for each APC.

- Using the median APC costs, we calculated the relative payment weights for each APC. As in prior years, we scaled all the relative payment weights to APC 0601,

Mid-level clinic visit, because it is one of the most frequently performed services in the hospital outpatient setting. This approach is consistent with that used in developing relative value units 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 2001 data, the median cost for APC 0601 is \$56.77.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes and wage index changes be made in a manner that assures that aggregate payments under the OPPI 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 proposed weights. Based on this comparison, we are proposing to make an adjustment of 1.04227 to the weights. The weights that we are proposing for 2003, which incorporate the recalibration adjustments explained in this section, are listed in Addendum A and Addendum B.

5. Procedures That Will Be Paid Only As Inpatient

Procedures

Before implementation of the OPPS, Medicare paid reasonable costs for services provided in the outpatient department. The claims submitted were subject to medical review by the fiscal intermediaries to determine the appropriateness of providing certain services in the outpatient setting. We did not specify in regulations those services that were appropriate to provide only in the inpatient setting and that, therefore, should be payable only when provided in that setting.

Section 1833(t)(1)(B)(i) of the Act gives the Secretary broad authority to determine the services to be covered and paid for under the OPPS. In the April 7, 2000 final rule, we identified procedures that are typically provided only in an inpatient setting and, therefore, would not be paid by Medicare under the OPPS (65 FR 18455). These procedures comprise what is referred to as the "inpatient list." The inpatient list specifies those services that are only paid when provided in an inpatient setting. These are services that require inpatient care because of the nature of the procedure, the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged, or the

underlying physical condition of the patient. As we discussed in the April 7, 2000 and the November 30, 2001 final rules, we use the following criteria when reviewing procedures to determine whether or not they should be moved from the inpatient list and assigned to an APC group for payment under the OPPS:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be performed in most outpatient departments.
- The procedure is related to codes we have already moved off the inpatient list.

We update the inpatient list as often as quarterly through program memoranda to reflect current advances in medical practice. 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. The Panel recommended that we solicit comments and further information about all these procedures except for CPT code 47001, which they recommended be removed from the inpatient list (see section II.A.2 above for a discussion of this and the other codes that the Panel

considered for removal from the inpatient list). These procedures are included in Table 6, with the exception of CPT code 33967, which we are not proposing to pay for under the OPPS for reasons that we explain in section II.A.2.

In preparing this proposed rule to update the OPPS for CY 2003, 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 found that there are procedures on the current ASC list, or procedures proposed for addition to the ASC list, or procedures recommended by commenters for addition to the ASC list that are assigned status indicator "C" under the OPPS. A review of 2001 physician claims data also revealed that physicians are performing some of these "C" status indicator procedures on Medicare beneficiaries on an outpatient basis. 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 that are set forth in 42 CFR 416.22. We believe that our payment policies for surgical procedures provided in an outpatient hospital setting and in the ASC setting should be consistent to the extent possible within the limitations imposed by statutory or regulatory requirements. So, we propose 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 includes the procedures that we are proposing to be removed from the inpatient list for payment under the OPPS. 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 solicit comments on whether the procedures in Table 6 should be paid under the OPPS. We also solicit comments on the APC assignment that we propose 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 ask 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 effective manner.

Following our review of the comments that we receive about the procedures in Table 6, we propose either to assign a CPT code to an APC for payment under the OPPS or, if the comments do not provide sufficient information and data to enable us to make a decision, to present the comments to the APC Panel at its 2003 meeting.

Table 6 - Procedures on the Inpatient List Proposed for Payment Under the OPFS in CY 2003

CPT Code	Proposed Status Indicator	Proposed 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)
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
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)

CPT Code	Proposed Status Indicator	Proposed APC	Description
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 EXCISIONS 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 April 7, 2000 OPSS final rule (65 FR 18452), 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). Payment to providers under the OPPS for PHPs represents the provider's overhead costs associated with the program. Because a day of care is the unit that defines the structure and scheduling of partial hospitalization services, effective for services furnished on or after August 1, 2000, we established a per diem payment methodology for the PHP APC. We analyzed the service components billed by hospitals over the course of a billing period and determined the median hospital cost of furnishing a day of partial hospitalization. We were unable to use CMHC data in computing the per diem because up until April 1, 2000, CMHCs were not required to report HCPCS codes. In addition, section 1833(t)(2)(C) of the Act requires that we establish relative payment weights based on median (or mean, at the election of the Secretary) hospital costs determined by 1996 claims and the most recent available cost report data. This analysis resulted in a per diem payment of \$202.19 effective August 1, 2000. This amount was updated effective January 1, 2001 and April 1, 2002 to \$206.82 and \$212.27.

Although we did not use CMHC data in establishing the initial APC for partial hospitalization (or in the updates made since then), in the April 7, 2000 final rule we made a

commitment to analyze future data from hospitals and CMHCs to determine if refinements to the per diem are warranted. Based on our review of 2001 claims data submitted under the OPSS, we have developed a payment rate for partial hospitalization following the same methodology used to establish all the APC payment amounts. However, because a day of care is the unit for PHP services, we computed the median cost of furnishing a day of partial hospitalization. Other than the unit of service being a day of care, the method we used to determine median costs for PHP is no different than that used for all other APCs as described in other sections of this proposed rule. The CY 2003 proposed payment rate for the partial hospitalization APC is \$256.96 per day, of which \$51.39 is the beneficiary's coinsurance.

We used calendar year 2001 bills from both hospitals and CMHCs. We used data from all the hospital bills reporting condition code 41, which identifies the claim as partial hospitalization. Since section 1866(e)(2) of the Act specifies that a CMHC is a provider of service "...only with respect to the furnishing of partial hospitalization services...", we used all bills from CMHCs. We used cost-to-charge ratios from the most recently available hospital and CMHC cost reports to develop costs from line item charges reported on bills. Since hospitals and CMHCs are now

required to report line item dates of service on claims, we used that data to refine our estimates of line item costs.

We then computed per diem costs by summing the line item costs on each bill and dividing by the number of days on each bill. Using this method of determining costs, preliminary per diem cost estimates for CMHCs were much higher than expected, in many cases more than twice the average per diem for inpatient psychiatric care and more than three times the hospital median PHP per diem cost. The data strongly suggests that the costs were reported incorrectly. We believe that the data are unusable without adjustment.

Closer examination of the CMHC cost report data showed that costs from CMHC finalized cost reports were considerably lower than costs from "as submitted" CMHC cost reports. To account for the difference between settled and as-filed cost report data, we computed the ratio of total final costs to total as-filed costs over a 3-year period (FYs 1998-2000) and calculated an average adjustment factor which we applied to the costs on each claim. The adjusted costs were summed, then divided by the number of days on that bill.

Treatment of Professional Services under PHP

Section 410.43 describes the conditions and exclusions of partial hospitalization services. That section lists the services that are separately covered and not paid as partial hospitalization services. The list includes--

- Physician services that meet the requirements of 42 CFR 415.102(a) for payment on a fee schedule basis;
- Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act;
- Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act;
- Qualified psychologist services, as defined in section 1861(ii) of the Act; and
- Services furnished to SNF residents as defined in 42 CFR 411.15(p).

Based on this section, in the April 7, 2000 OPPS rule, we stated that the APC for partial hospitalization represents the provider's overhead costs, support staff, and the services of clinical social workers (CSWs) and occupational therapists (OTs), whose professional services are considered to be partial hospitalization services for which Medicare payment is made to the provider. Before implementation of the OPPS, the services of CSWs and OTs in

a PHP were billed by the hospitals to the fiscal intermediaries and paid on a reasonable cost basis.

We have looked carefully at the differences between the cost experiences of CMHCs and of hospitals with respect to PHP services, as well as how payment is made for other hospital outpatient psychiatric services, to identify areas where improvements can be made in OPSS. One of the areas in which we identified discrepancies was in the coverage of CSW services. The way in which CSW services are currently billed and paid depends upon the circumstances under which CSW services are provided. In some settings, payment for CSW services is part of a bundled payment. In other settings, separate payment for CSW services is made.

Generally, CSW services furnished to hospital outpatients are bundled, which means that only the hospital may bill for such services. However, payment for CSW professional services furnished to hospital outpatients is made under the physician fee schedule. Therefore, the hospital outpatient department bills separately the Part B carrier for CSW services furnished to outpatients who are not in a PHP. CSW professional services are paid at 75 percent of the clinical psychologist fee schedule.

However, when CSWs furnish services to hospital outpatients or a CMHC under a partial hospitalization

program, hospitals may not bill separately for the services of a CSW. Instead, for coverage and payment purposes, the services are recognized as partial hospitalization services. Partial hospitalization services are billed by hospitals and CMHCs to the fiscal intermediaries and paid the OPSS PHP APC per diem amount.

The different methodologies for payment of CSW services has proven both confusing and burdensome for hospitals because they must implement separate billing schemes for CSW services depending upon whether an individual outpatient is admitted to a PHP program or to any other hospital outpatient psychiatric program. We believe that these challenges have resulted in incorrect reporting by hospitals which has led to an under-representation of CSW services in the OPSS PHP APC per diem amount.

To facilitate proper billing and to ensure comparable reporting of costs by hospitals and CMHCs, we are proposing to allow separate payment for CSW services furnished in CMHCs. This means that both hospitals and CMHCs will bill the carrier for CSW services furnished to PHP patients. Therefore, we are proposing to amend §410.43(b) to add clinical social worker 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. We believe this change will allow CSW services to be more appropriately reflected in both settings as part of PHPs.

III. 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. As originally enacted by the BBRA, this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act, Pub. L. 107-186; current drugs, biologic agents, and brachytherapy devices used for the treatment of cancer; and current radiopharmaceutical drugs and biological products.

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), Pub. L. 106-554, enacted December 21, 2000).

Transitional pass-through payments are also required for certain "new" medical devices, drugs, and biological

agents that were not being paid for as a hospital outpatient service as of December 31, 1996 and whose cost is "not insignificant" in relation to the OPPS payment for the procedures or services associated with the new device, drug, or biological. Under the statute, transitional pass-through payments 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://www.hcfa.gov/pubforms/transmit/A0140.pdf> and <http://www.hcfa.gov/pubforms/transmit/A0141.pdf>, respectively.

Transmittal A-01-41 includes a list of the initial device categories 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://www.hcfa.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 will respond to public comments on that interim final rule in the final rule 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 process to apply for transitional pass-through payment for eligible drugs and biological agents or for additional device categories can be found on respective pages on our web site at <http://www.hcfa.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://www.hcfa.gov/Medicare/hopsmain.html>.

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

We will make an estimate of pass-through spending in 2003 using the methodology described below. Making an estimate of pass-through spending in 2003 entails estimating spending for two groups of items. The first group consists of those items for which we have claims data (that is, items that were eligible in 2001 and that will continue to be eligible in 2003). The second group consists of those items for which we have no direct claims data (that is, items that became or will become eligible in 2002 and will retain pass-through status and items that will be newly eligible beginning in 2003).

To estimate 2003 pass-through spending for device categories in the first group, we will use volume and hospital cost (derived from charges on claims using cost-to-charge ratios) information from 2001 claims data. This information will be projected forward to 2003 levels using appropriate inflation and utilization factors. For

existing categories with no claims data in 2001 that are or will be active in 2002, we will follow the method described in the November 2, 2001 final rule (66 FR 55857). We will use price information from manufacturers and volume estimates from claims related to procedures that use the devices in question. This information will be projected forward to 2003 using appropriate inflation and utilization factors to estimate 2003 pass-through spending for this group of categories. For categories that become eligible in 2003, we will use the same method as described for categories that are newly active in 2002. Any new categories for 2003 will be announced after the publication of this proposed rule but prior to the publication of the final rule. Therefore the estimate of pass-through spending will incorporate pass-through spending for categories made effective January 1, 2003.

To estimate 2003 pass-through spending for drugs, biologicals, and radiopharmaceuticals, in the first group, we will use volume data from 2001 claims and the average wholesale price (AWP) as published in the July 2002 Red Book. This information will be projected forward to 2003 using the appropriate utilization factor. (Because 2003 payment rates for pass-through drugs will be based on the July 2002 AWP, we do not apply an inflation factor.) The

pass-through amount for drugs, biologicals, and radiopharmaceuticals is the difference between the payment rate (that is, 95 percent of the AWP) and the amount that would have been included in the payment rate of its associated APC had the drug, biological, or radiopharmaceutical been packaged. Section V.E. describes this methodology. To estimate pass-through spending for drugs in this group, for each drug we will multiply the drug's estimated utilization times the pass-through amount (for example, the difference between 95 percent of AWP for the drug and the amount included in the payment rate for its associated APC). For most drugs, the pass-through amount will be based on the weighted average ratios described in Section IV.E. However some drugs may fall into two other classes. The first class includes a drug that is new and for which there are no previously existing costs in an associated APC. For such a drug, we propose that the pass-through amount would be 95 percent of the AWP (because there are no previously existing costs in an associated APC) and there will be no copayment (because there are no previously existing costs in an APC on which to base a copayment). The second class includes a drug that is new and is a substitute for only one drug whose cost is recognized in the OPPS through an unpackaged APC.

For drugs in this second class, we propose that the pass-through amount would be the difference between 95 percent of the AWP for the pass-through drug and the payment rate for the comparable dose of the associated drug's APC. The copayment would be based on the payment rate of its associated APC.

For existing drugs, biologicals, and radiopharmaceuticals for which we have no claims data in 2001 and which are active or will be active in 2002 as well as for drugs, biologicals, and radiopharmaceuticals, we will derive volume estimates from information submitted by manufacturers as well as other sources (such as, peer-reviewed clinical studies) and the AWP as published in the July 2002 Red Book. This information will be projected forward to 2003 using the appropriate utilization factor. Again, because 2003 payment rates for pass-through drugs will be based on the July 2002 AWP, we do not apply an inflation factor. To estimate pass-through spending for drugs in this group, for each drug we will multiply the drug's estimated utilization times the pass-through amount. For most drugs, these amounts will be based on the weighted average ratios described in Section IV.E. However some drugs may fall into two other classes. The first class includes a drug that is new and has no previously existing

costs included in an associated APC. For such a drug, we propose that the pass-through amount would be 95 percent of the AWP (because there are no previously existing costs included in an APC) and there would be no copayment (because there are no previously existing costs in an APC on which to base a copayment). The table below shows two such drugs, Y-90 Zevalin and IN-111 Zevalin. The second class includes a drug that is new and is a substitute for only one drug that is recognized in the OPPS, through an unpackaged APC. The table below shows one such drug, Darbepoetin alfa, which is a new substitute of epoetin. For drugs in this second class, the pass-through amount will be the difference between 95 percent of the AWP for the pass-through drug and the payment rate for the comparable dose of the associated drug's APC. The copayment will be based on the payment rate of its associated APC. For drugs, biologicals, and radiopharmaceuticals that may receive pass-through status effective January 1, 2003, we will use the same methodology as described for drugs, biologicals, and radiopharmaceuticals that received pass-through status in 2002. Any new pass-through drugs, biologicals, and radiopharmaceuticals effective beginning in 2003 will be announced after the publication of this proposed rule but

prior to the publication of the final rule. Therefore the estimate of pass-through spending will incorporate pass-through spending for these drugs, biologicals, and radiopharmaceuticals made effective January 1, 2003.

Finally, we will incorporate an estimate of pass-through spending for items that become eligible later in 2003 (that is, April 1, 2003; July 1, 2003; and October 1, 2003) based on estimates for items that will become eligible for pass-through status January 1, 2003. Specifically, we will assume a proportionate amount of spending for items that become eligible later in the year while making an adjustment to account for the fact that items made eligible later in the year will not have received pass-through payments for the entire year.

After using the methodologies described above to determine projected 2003 pass-through spending for the groups of devices, drugs, biologicals, and radiopharmaceuticals described above, 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 this table was developed. We are uncertain whether pass-through spending in 2003 will exceed \$457 million or 2.5 percent of total OPPS spending. We have not yet completed the estimate of pass-through spending for a number of drugs. In particular, we are in the process of obtaining additional information about the utilization volume for several pass-through drugs. We invite comments on the methodology described above as well as the assumptions shown in the table below including anticipated utilization and utilization not yet determined. More information regarding the assumptions used to create these estimates is available at

<http://cms.hhs.gov/regulations/regnotices.asp>.

Table X
HCPC

	APC	DRUG, Biological	2002 Payment Rate	2001 Utilization	2003 Pass- through Payment Portion	2003 Estimated Utilization	2003 Anticipated Pass-Through Payment
Existing Pass-through Drugs/ biologicals							
A9700	9016	Echocardiography Contrast*	\$118.75	300,000	\$34.44	368,686	\$12,696,607.35
C1774	734	Darbepoetin alfa, 1 mcg	\$4.74	6136252	\$1.37	7,541,157	\$10,366,074.10
C1058	1058	TC 99M oxidronate, per vial	\$36.74	4,000	\$10.65	4,916	\$52,375.96
C1064	1064	I-131 cap, each add mCi	\$5.86	4,575	\$1.88	5,622	\$485,208.00
C1065	1065	I-131 sol, each add mCi	\$15.81	4,575	\$5.06	5,622	\$1,309,068.00
C1775	1775	FDG, per dose (4-40 mCi/ml)	\$475.00	30,000	\$137.75	36,869	\$5,078,642.94
J9219	7051	Leuprolide acetate implant	\$5,399.80	66	\$1,565.94	81	\$127,014.83
J9017	9012	Arsenic Trioxide	\$23.75		\$6.89	TBD	To be determined
J7517	9015	Mycophenolate mofetil oral	\$2.40		\$0.70	TBD	To be determined
J0587	9018	Botulinum toxin type B	\$8.79		\$2.55	TBD	To be determined
C9019	9019	Caspofugen acetate, 5 mg	\$34.20		\$9.92	TBD	To be determined
C9110	9110	Alemtuzumab, per 10mg/ml	\$486.88		\$141.20	517	\$72,997.92
C9111	9111	Inj. Bivalrudin, 250 mg vial	\$397.81		\$115.36	TBD	To be determined
C9112	9112	Perflutren lipid micro, 2ml	\$148.20	300,000	\$42.98	368,686	\$15,845,365.98
C9113	9113	Inj Pantoprazole sodium, vial	\$22.80		\$6.61	TBD	To be determined

C9114	9114	Nesiritide, per 1.5 mg vial	\$433.20	\$125.63	TBD	To be determined
C9115	9115	Zoledronic acid, 2 mg	\$406.78	\$117.97	TBD	To be determined
C9200	9200	Orcel, per 36 cm2	\$1,135.25	\$329.22	TBD	To be determined
C9201	9201	Dermagraft, per 37.5 sq cm	\$577.60	\$167.50	TBD	To be determined

**Pass-through
Drugs/
Biologicals
Effective
October 2002**

C9116	9116	Ertapenem sodium	\$36.24	\$10.51	TBD	To be determined
C9117	9117	Y-90 Zevalin	\$19,181.44	\$19,181.44	9,000	\$172,632,960.00
C9118	9118	IN-111 Zevalin	\$2,769.65	\$2,769.65	9,000	\$24,926,850.00
C9119	9119	Pegfilgrastim	\$2,802.50	\$2,367.13	85,258	\$201,815,396.40

**Pass-through
Devices**

C1765	1754	Adhesion barrier	256	261	\$20,011.00
C1783	1783	Ocular implant, aqueous drainage	2000	2042	\$1,327,300.00
C1888	1888	Endovascular, non-cardiac	184	188	\$136,300.00
C1900	1900	Lead, left ventricular	1000	1021	\$2,042,000.00
C2618	2618	Probe, cryoablation	1120	1144	\$531,106.00

C. Expiration of Transitional Pass-Through Payments in
Calendar Year 2003

1. Devices

Section 1833(t)(6)(B)(iii) of the Act requires that a category of devices be eligible for transitional pass-through payments for at least 2, but not more than 3, years. This period begins with the first date on which a transitional pass-through payment is made for any medical device that is described by the category. We propose that 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, cited in section III.A.) To establish the expiration date for the category codes listed in Table 7, 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 propose 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 7 - List of Pass-Through Device Categories with Proposed 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

	HCPCS Codes	Category Long Descriptor	Date First Populated	Expiration Date
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
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,	8/1/00	12/31/02

	HCPCS Codes	Category Long Descriptor	Date First Populated	Expiration Date
		permanent (implantable)		
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

	HCPCS Codes	Category Long Descriptor	Date First Populated	Expiration Date
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
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.

We have carefully considered 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. One consideration under the OPPS is the need to enable beneficiary access to new, and often costly, medical technology. We have also had to assess the extent to which the most recently available data that are the basis for prospectively setting payment rates for services within the APC system adequately reflect the costs incurred by hospitals to furnish this new technology. Having considered these factors, we propose 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 III.C.2.)

The methodology that we propose to use to package pass-through device costs is consistent with the

methodology for packaging that we describe in section II.B.4.b. 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.

We discuss in section II.B.4.a.(2), issues related to coding and billing for pass-through devices in 2001 and how our analysis of the claims data suggests that in some instances charges for devices were billed in revenue centers and in other instances with a device-specific or device category "C" code. We did not want to lose the device costs billed by hospitals through revenue centers in developing our relative weights for APCs, yet we were unable to separate the device costs from other costs included in the revenue centers. This problem is resolved by our proposal to package the costs of both the device "C" codes and the billed revenue centers, whichever appears on

the claim. We are confident that this method will allow us to capture all device related costs billed by hospitals.

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 propose 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 propose 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 propose to reject line items containing a "C" code for a device category scheduled to expire effective January 1, 2003.

2. Drugs and Biologicals (Including Radiopharmaceuticals, Blood, and Blood Products)

Under the OPSS, we currently pay for drugs and biologicals, including radiopharmaceuticals, blood, and blood products, in one of three ways: packaged payment, separate APCs and transitional pass-through payment.

Packaged Payment

As we explained in the April 7, 2000 final rule, we generally package the cost of drugs and biologicals into the APC payment rate for the primary procedure or treatment with which the drugs are usually furnished (65 FR 18450). Hospitals do not receive separate payment from Medicare for packaged items and supplies, and hospitals may not bill beneficiaries separately for any such packaged items and supplies whose costs are recognized and paid for within the national OPSS payment rate for the associated procedure or service. (Transmittal A-01-133, a Program Memorandum issued to Intermediaries on November 20, 2001, explains in greater detail the rules regarding separate payment for packaged services). Hospitals bill for costs directly related and integral to performing a procedure or furnishing a service using a revenue center or packaged HCPCS code (status indicator "N"). As discussed earlier in section II.B.4.a(2), we list the packaged services, by revenue center, that we use to calculate per-service costs.

As specified in the regulations at §419.2(b), costs directly related and integral to performing a procedure or furnishing a service on an outpatient basis are included in the determination of OPPS payment rates for the procedure or service. For example, sedatives administered to patients while they are in the preoperative area being prepared for a procedure are supplies that are integral to being able to perform the procedure. Similarly, mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic ointments, and ocular hypotensives that are administered to the patient immediately before, during, or following an ophthalmic procedure are considered an integral part of the procedure without which the procedure could not be performed. The costs of these items are packaged into and reflected within the OPPS payment rate for the procedure. Likewise, barium or low osmolar contrast media are supplies that are integral to a diagnostic imaging procedure as is the topical solution used with photodynamic therapy furnished at the hospital to treat non-hyperkeratotic actinic keratosis lesions of the face or scalp. Local anesthetics such as marcaine, lidocaine (with or without epinephrine) and antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of a

procedure, are other examples. The hospital furnishes these items while the patient is in the hospital and registered as an outpatient for the purpose of receiving a therapy, treatment, procedure, or service. These and other such supplies may be furnished pre-operatively, while the patient is being prepared for a procedure; intra-operatively, while the procedure is being performed; or post-operatively, while the patient is in the recovery area prior to discharge. Or, these items may be part of an E/M service furnished during a clinic visit or in the emergency department. All of these supplies are directly related and integral to the performance of a separately payable therapy, treatment, procedure, or service with which they are furnished. Therefore, we do not generally recognize them as separately payable services. We package their cost into the cost of the primary procedure, and we pay for them as part of the APC payment.

**Separate APCs for Drugs Not Eligible for Transitional
Pass-Through Payment**

There are certain new technology drugs and biologicals that are not eligible for transitional pass-through payments but for which we have made separate payment. Beginning with the April 7, 2000 rule (65 FR 18476), we created separate new technology APCs for these drugs and

biologicals as well as devices. For example, we did not package into the emergency room visit APCs the various drugs classified as tissue plasminogen activators (TPAs) and other thrombolytic agents that are used to treat patients with myocardial infarctions. We also did not package the costs of certain vaccines into the payment for visits or procedures. Rather, we created temporary individual APC groups for these drugs to allow separate payment so as not to discourage their use where appropriate. In the case of blood and blood products, wide variations in patient requirements convinced us that we should pay for these items separately rather than packaging their costs into the procedural APCs. Moreover, the Secretary's Advisory Council on Blood Safety and Access recommended that blood and blood products be paid separately to ensure that there were no incentives that would be inconsistent with the promotion of blood safety and access.

In the case of the other drugs and vaccines that we did not package into payment for visits or procedures, we paid separately for them because we wanted to avoid creating an incentive to cease providing these drugs when they were medically indicated.

We based the payment rate for the APCs for these drugs and biologicals on median hospital acquisition costs. To determine the hospital acquisition cost for the drugs, we imputed a cost using the same ratios of drug acquisition cost to AWP that we discuss below in connection with calculating acquisition costs for transitional pass-through drug payments. That is, we multiplied the AWP for the drug by the applicable ratio (sole or multisource drug) based on data collected in an external survey of hospital drug acquisition costs.

We set beneficiary copayment amounts for these drug and biological APCs at 20 percent of the imputed acquisition cost. In 2003 we will use status indicator "K" to denote the APCs for drugs and biologicals (including blood and blood products) and certain brachytherapy seeds that are paid separately from and in addition to the procedure or treatment with which they are associated but that are not eligible for transitional pass-through payment.

Transitional Pass-Through Payments for Eligible Drugs and Biologicals

BBRA provided for special transitional pass-through payments for a period of 2 to 3 years for the following

drugs and biologicals (pass-through payments for devices are addressed in section III.C.1 of this proposed rule):

- Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act.
- Current drugs and biologic agents used for treatment of cancer.
- Current radiopharmaceutical drugs and biological products.
- New drugs and biological agents.

In this context, "current" refers to those items for which hospital outpatient payment was being made on August 1, 2000, the date on which the OPSS was implemented. A "new" drug or biological is a product that is not paid under the OPSS as a "current" drug or biological, was not paid as a hospital outpatient service before January 1, 1997, and for which the cost is not insignificant in relation to the payment for the APC with which it is associated.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs as the amount by which the amount determined under section 1842(o) of the Act, that is, 95 percent of the applicable average wholesale price (AWP), exceeds the difference between 95 percent of the applicable AWP and the portion of the otherwise

applicable fee schedule amount (that is, the APC payment rate) that the Secretary determines is associated with the drug or biological. Therefore, in order to determine the pass-through payment amount, we first had to determine the cost that was packaged for the drug or biological within its related APC. In order to determine this amount, we used data on hospital acquisition costs for drugs from a survey that is described more fully in the April 7, 2000 and the November 30, 2001 final rules. The ratio of hospital acquisition cost, on average, to AWP that we used is as follows:

- For sole-source drugs, the ratio of acquisition cost to AWP equals 0.68.
- For multisource drugs, the ratio of acquisition cost to AWP equals 0.61.
- For multisource drugs with generic competitors, the ratio of acquisition cost to AWP equals 0.43.

Section 1833(t)(6)(C)(i) of the Act specifies that the duration of transitional pass-through payments for current drugs and biologicals must be no less than 2 years nor any longer than 3 years beginning on the date that the OPDS is implemented. Therefore, the latest date for which current drugs that have been in transitional pass-through status since August 1, 2000 will be eligible for transitional

pass-through payments is July 31, 2003. We propose to remove these drugs from transitional pass-through status effective January 1, 2003 because the law gives us the discretion to do so and because we generally implement annual OPPS updates on January 1 of each year. We would be in violation of the law if we were to not remove these drugs and biologicals from transitional pass through status before August 2, 2003. The next new OPPS that will go into place will not be effective until January 1, 2004, at which time, the statute's 3-year limit on pass-through payments for these drugs would have been exceeded. We further propose to remove from transitional pass-through status, beginning January 1, 2003, those drugs for which transitional pass-through payments were made effective on or prior to January 1, 2001 because the law gives us the discretion to do so and we believe that, to the extent possible, payments should be made under the OPPS, without pass-through payment, when the law permits, as it does in this case.

As explained above, our policy has been to package payment for drugs and biologicals into the payment for the procedure or service to which the drug is integral and directly related. In general, packaging the costs of items and services into the payment for the primary procedure or

service with which it is associated encourages hospital efficiencies and also enables hospitals to manage their resources with maximum flexibility. Packaging costs into a single aggregate payment for a service procedure or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. Our proposal to package the costs of devices that we discuss in section III.C.1 of this preamble is based on this principle. As we refine the OPPS in the future, we intend to continue to package, to the maximum possible extent, the costs of any items and services that are furnished with an outpatient procedure or service into the APC payment for services with which it is billed.

Notwithstanding our commitment to package as many costs as possible, we are aware of concerns that were presented at the April 5, 2002 Town Hall meeting and that have been brought to our attention by various interested parties, that packaging payments for certain drugs, especially those that are particularly expensive or rarely used, might result in insufficient payments to hospitals, which could adversely affect beneficiary access to medically necessary services.

The options that we considered included packaging the costs of all drugs and biologicals, both those with status

indicator "K" in 2002 and those that would no longer receive pass-through payments in 2003, or continuing to make separate payment for both categories of drugs and biologicals through separate APCs. After careful consideration of the various options for 2003, we propose to package the cost of many drugs for which separate payment is made currently. But we also propose to continue making separate payment for orphan drugs (as defined below), blood and blood products, vaccines that are paid under a benefit separate from the outpatient hospital benefit (that is, influenza, pneumococcal pneumonia, and hepatitis B), and certain higher cost drugs as explained below. The payment rates for those drugs for which we would make separate payment in 2003 would be an APC payment rate based on a relative weight calculated in the same way that relative weights for procedural APCs are calculated.

Orphan Drugs

We recognize that orphan drugs that are used solely for an orphan condition or conditions are generally expensive and, by definition, are rarely used. We believe that if the cost of these drugs were packaged into the payment for an associated procedure or visit, the payment for the procedure might be insufficient to compensate a hospital for the typically high cost of this special type

of drug. Therefore, we propose to establish separate APCs to pay for those orphan drugs that are used solely for orphan conditions.

To identify the orphan drugs for which we would continue to make separate payment, we applied the following criteria:

- The drug must be designated as an orphan drug by FDA and approved by FDA for the orphan condition.
- The current United States Pharmacopoeia Drug Information (USPDI) shows that the drug had neither an approved use for other than an orphan condition nor an off label use for conditions other than the orphan condition. There are three orphan drugs that are used solely for orphan conditions for which we propose to make separate payment: J0205 Alglucerase injection (APC 0900); J0256 Alpha 1 proteinase inhibitor (APC 0901); and J09300 Gemtuzumab ozogamicin (APC 9004).

Blood and Blood Products

From the onset of the OPPS, we have made separate payment for blood and blood products either in APCs with status indicator "K" or as pass-through drugs and biologicals with status indicator "G" rather than packaging them into payment for the procedures with which they were administered. As we explained in the April 7, 2000 final

rule (65 FR 18449), the high degree of variability in blood use among patients could result in payment inequities if the costs of blood and blood products were packaged with their administration. We also want to ensure that costs associated with blood safety testing are fully recognized. The safety of the nation's blood supply continues to be among the highest priorities of the Secretary's council on Blood Safety and Access. Therefore, we propose to continue to pay separately for blood and blood products.

Vaccines Covered under a Benefit Other Than OPPS

Outpatient hospital departments administer large numbers of the vaccines for influenza (flu), pneumococcal pneumonia (PPV), and hepatitis B, typically by participating in immunization programs encouraged by the Secretary because these vaccinations greatly reduce death and illness in vulnerable populations. In recent years, the availability and cost of the vaccines (particularly the flu vaccine) have varied considerably. We want to avoid creating any disincentives to provide these important preventative services that might result from packaging their costs into those of primary procedures, visits, or administration codes. Therefore, we propose to pay for these vaccines under OPPS through the establishment of separate APCs.

Higher Cost Drugs

While our preferred policy is to package the cost of drugs and other items into the cost of the procedures with which they are associated, we are concerned that beneficiary access to care may be affected by packaging certain higher cost drugs. For this reason, we propose to allow payment under separate APCs for high cost drugs for an additional year while we further study various payment options. Specifically, we propose to pay separately for drugs for which the median cost per line (cost per unit multiplied by the number of units billed on the claim) exceeded \$150, as determined below.

To establish a reasonable threshold for determining which drugs we would pay under separate APCs rather than through packaging, we calculated the median cost per unit using 2001 claims data for each of the drugs for which transitional pass-through payment ceases January 1, 2003 and for those additional drugs that we have paid separately (status indicator "K") since the outset of OPPS. We excluded from these calculations the orphan drugs, vaccines, and blood and blood products discussed above. The unit median represents the cost per single unit dose of the drug as described by its HCPCS code. Because many drugs are used and billed in multiple unit doses, we then

multiplied the median cost per unit for the drug by the average number of units that were billed per line. The average number of units per drug equals the total units divided by the total number of times the drug was billed. This calculation gave us an approximate median cost per line for the drug. We viewed this as being the approximate cost per administration because we believed that a single administration of a drug was billed as a single line item on a claim and that the correct number of units was placed in the "units" field of the claim form. We then arrayed the median cost per line in ascending order and examined the distribution. A natural break occurs at \$150 per line, the midpoint of a \$10 span between the drug immediately above and below the \$150 point. Within the array, approximately 61 percent of the drugs fall below the \$150 point and 39 percent of the array are above the point. Among the drugs that we propose to package are some radiopharmaceuticals, vaccines, anesthetics, and anticancer agents. After including the costs of packaged drugs in the services with which they were provided, we noted that the median costs of those services increased. For example, based on 2001 data, APC 117, Chemotherapy Administration by Infusion Only, showed a median cost before packaging of \$129.53 and showed a median cost after packaging of

\$210.36. Similarly, APC 118, Chemotherapy administration by both infusion and another technique, showed a median cost before packaging of \$136.00 and a median cost after packaging of \$309.65. We believe that this appropriately represents the cost of packaged drugs on a per administration basis. However, in particular, we solicit comments that address specific alternative protocols we might use when several packaged drugs whose total cost significantly exceeds the applicable APC payment amount may be administered to a patient on the same day (for example, multiple agent cancer chemotherapy).

We request comments on the factors we considered in determining which drugs to package in 2003. We are particularly interested in comments with respect to the exclusion of high cost drugs from packaging. We are continuing to analyze the effect of our drug packaging proposal to assess whether the \$150 threshold should be adjusted to avoid significant overpayments or underpayments for the base APCs relative to the median costs of the individual drugs packaged into the APCs. Depending on this analysis, we may revise our threshold or criteria for packaging in the final rule for 2003. We expect to further consider each of these exclusions for packaging when we develop our proposals for the 2004 OPPS.

Although we expect to expand packaging of drugs to package payment for more drugs into the APC for the services with which they are billed, we are, nonetheless, requesting comments on alternatives to packaging. One example of an alternative approach is to use different criteria from those we propose in this proposed rule to identify the drugs to package into procedure APCs and the drugs to pay separately. We could package all drugs for which the median cost was less than \$500 or alternatively package drugs for which the median costs was less than \$100. Another alternative approach would be to create APCs for groups of drugs based on their costs. Under such an approach we could group drugs with costs between \$0 and \$100 and pay at the mid-point -- \$50. The next group could consist of drugs with a median cost between \$100 and \$250 and pay at the mid-point -- \$175. This approach would be similar to that employed for new technology services. Another approach would be to create separate APCs for each drug. Under this approach we would create a separate APC for each drug (regardless of its median cost) and use its relative weight to calculate a payment rate for the drug. We welcome a full discussion of the alternatives as we determine the best way to ensure that hospitals are paid appropriately for the drugs they administer to the Medicare

beneficiaries whom they treat in their outpatient departments.

Table 8 lists drugs and biologicals for which separate payment is currently being made in 2002 with either status indicator "K" or "G" and whose costs we propose to package in 2003. Drugs that we propose to pay for separately in 2003 are designated in Addendum B by status indicator "K" or "G."

TABLE 8 - Drugs and Biologicals Separately Payable in CY 2002

HCPCS	Short Description
90296	Diphtheria antitoxin
90375	Rabies ig, im/sc
90376	Rabies ig, heat treated
90378	Rsv ig, im, 50mg
90379	Rsv ig, iv
90385	Rh ig, minidose, im
90389	Tetanus ig, im
90393	Vaccina ig, im
90396	Varicella-zoster ig, im
90471	Immunization admin
90476	Adenovirus vaccine, type 4
90477	Adenovirus vaccine, type 7
90585	Bcg vaccine, percut
90586	Bcg vaccine, intravesical
90632	Hep a vaccine, adult im
90633	Hep a vacc, ped/adol, 2 dose
90634	Hep a vacc, ped/adol, 3 dose
90645	Hib vaccine, hboc, im
90646	Hib vaccine, prp-d, im
90647	Hib vaccine, prp-omp, im
90648	Hib vaccine, prp-t, im
90665	Lyme disease vaccine, im
90675	Rabies vaccine, im
90676	Rabies vaccine, id
90680	Rotovirus vaccine, oral
90690	Typhoid vaccine, oral
90691	Typhoid vaccine, im

HCPCS	Short Description
90692	Typhoid vaccine, h-p, sc/id
90700	Dtap vaccine, im
90701	Dtp vaccine, im
90702	Dt vaccine < 7, im
90703	Tetanus vaccine, im
90704	Mumps vaccine, sc
90705	Measles vaccine, sc
90706	Rubella vaccine, sc
90707	Mmr vaccine, sc
90708	Measles-rubella vaccine, sc
90710	MmrV vaccine, sc
90712	Oral poliovirus vaccine
90713	Poliovirus, ipv, sc
90716	Chicken pox vaccine, sc
90717	Yellow fever vaccine, sc
90718	Td vaccine > 7, im
90719	Diphtheria vaccine, im
90720	Dtp/hib vaccine, im
90721	Dtap/hib vaccine, im
90725	Cholera vaccine, injectable
90727	Plague vaccine, im
90733	Meningococcal vaccine, sc
90735	Encephalitis vaccine, sc
90749	Vaccine toxoid
A4642	Satumomab pendetide per dose
A9500	Technetium TC 99m sestamibi
A9502	Technetium TC99M tetrofosmin
A9503	Technetium TC 99m medronate
A9504	Technetium tc 99m apcitide
A9505	Thallous chloride TL 201/mci
A9508	Iobenguane sulfate I-131
A9510	Technetium TC99m Disofenin
A9700	Echocardiography Contrast
C1066	IN 111 satumomab pendetide
C1079	CO 57/58 per 0.5 uCi
C1087	I-123 per 100 uCi
C1094	TC99Malbumin aggr,per 1.0mCi
C1097	TC 99M MEBROFENIN, PER Vial
C1098	TC 99M PENTETATE, PER Vial
C1099	TC 99M PYROPHOSPHATE,PER Via
C1166	CYTARABINE LIPOSOMAL, 10 mg
C1188	I-131 cap, per 1-5 mCi
C1200	TC 99M Sodium Glucoheptonat
C1201	TC 99M SUCCIMER, PER Vial
C1202	TC 99M SULFUR COLLOID, Vial
J2020	Linezolid inj, 200mg
J7525	Tacrolimus inj, per 5 mg
C9007	Baclofen Intrathecal kit-1am

HCPCS	Short Description
C9008	Baclofen Refill Kit-500mcg
J0706	Caffeine Citrate, inj, 1ml
C9100	Iodinated I-131 Albumin
C9102	51 Na Chromate, 50mCi
C9103	Na Iothalamate I-125, 10 uCi
J0150	Injection adenosine 6 MG
J0350	Injection anistreplase 30 u
J0640	Leucovorin calcium injection
J0706	Caffeine Citrate, inj, per 5 mg
J1245	Dipyridamole injection
J1260	Dolasetron mesylate
J1325	Epoprostenol injection
J1327	Eptifibatide injection
J1436	Etidronate disodium inj
J1438	Etanercept injection
J1565	RSV-ivig
J1570	Ganciclovir sodium injection
J1620	Gonadorelin hydroch/ 100 mcg
J1626	Granisetron HCl injection
J1670	Tetanus immune globulin inj
J1830	Interferon beta-1b / .25 MG
J2260	Inj milrinone lactate / 5 ML
J2275	Morphine sulfate injection
J2405	Ondansetron hcl injection
J2765	Metoclopramide hcl injection
J2770	Quinupristin/dalfopristin
J2820	Sargramostim injection
J2995	Inj streptokinase /250000 IU
J2997	Alteplase recombinant
J3010	Fentanyl citrate injeciton
J3280	Thiethylperazine maleate inj
J3365	Urokinase 250,000 IU inj
J7310	Ganciclovir long act implant
J7316	Sodium hyaluronate injection, per 5 mg
J7500	Azathioprine oral 50mg
J7501	Azathioprine parenteral
J7506	Prednisone oral
J7516	Cyclosporin parenteral 250mg
J8510	Oral busulfan
J8530	Cyclophosphamide oral 25 MG
J8600	Melphalan oral 2 MG
J8610	Methotrexate oral 2.5 MG
J9000	Doxorubic hcl 10 MG vl chemo
J9020	Asparaginase injection
J9031	Bcg live intravesical vac
J9050	Carmus bischl nitro inj
J9070	Cyclophosphamide 100 MG inj
J9093	Cyclophosphamide lyophilized

HCPCS	Short Description
J9100	Cytarabine hcl 100 MG inj
J9120	Dactinomycin actinomycin d
J9130	Dacarbazine 10 MG inj
J9181	Etoposide 10 MG inj
J9190	Fluorouracil injection
J9212	Interferon alfacon-1
J9213	Interferon alfa-2a inj
J9214	Interferon alfa-2b inj
J9215	Interferon alfa-n3 inj
J9230	Mechlorethamine hcl inj
J9250	Methotrexate sodium inj
J9270	Plicamycin (mithramycin) inj
J9320	Streptozocin injection
J9340	Thiotepa injection
J9360	Vinblastine sulfate inj
J9370	Vincristine sulfate 1 MG inj
Q0163	Diphenhydramine HCl 50mg
Q0164	Prochlorperazine maleate 5mg
Q0166	Granisetron HCl 1 mg oral
Q0167	Dronabinol 2.5mg oral
Q0169	Promethazine HCl 12.5mg oral
Q0171	Chlorpromazine HCl 10mg oral
Q0173	Trimethobenzamide HCl 250mg
Q0174	Thiethylperazine maleate10mg
Q0175	Perphenazine 4mg oral
Q0177	Hydroxyzine pamoate 25mg
Q0179	Ondansetron HCl 8mg oral
Q0180	Dolasetron mesylate oral
Q2002	Elliotts b solution per ml
Q2003	Aprotinin, 10,000 kiu
Q2004	Bladder calculi irrig sol
Q2007	Ethanolamine oleate 100 mg
Q2008	Fomepizole, 15 mg
Q2009	Fosphenytoin, 50 mg
Q2010	Glatiramer acetate, per dose
Q2013	Pentastarch 10% solution
Q2014	Sermorelin acetate, 0.5 mg
J2940	Somatrem injection
Q2018	Urofollitropin, 75 iu
Q2021	Lepirudin
Q3002	Gallium ga 67
Q3004	Xenon xe 133
Q3005	Technetium tc99m mertiatide
Q3006	Technetium tc99m gluceptate
Q3007	Sodium phosphate p32
Q3009	Technetium tc99m oxidronate
Q3010	Technetium tc99mlabeledrbc

3. Brachytherapy

Section 1833(t)(6) of the Act requires us to establish transitional pass-through payments for devices of brachytherapy. As of August 1, 2000, we established item-specific device codes including codes for brachytherapy seeds, needles, and catheters. Effective April 1, 2001, we established category codes for brachytherapy seeds on a per seed basis (one for each isotope), brachytherapy needles on a per needle basis, and brachytherapy catheters on a per catheter basis. Because initial payment was made for a device in each of these categories in August 2000, we propose that these categories (and the transitional pass-through payments) will be discontinued as of January 1, 2003. Furthermore, as discussed above, we propose that there will be no grace period for billing these category codes.

We received comments, both in writing and at the April 2002 Town Hall meeting, recommending that we continue to make separate payment for brachytherapy seeds. The basis for this recommendation is that the number of brachytherapy seeds implanted per procedure is variable. These commenters stated that the number and type of seeds implanted in a given patient depends on the type of tumor, its size, extent, and biology, and the amount of

radioactivity contained in each seed. For example, a given type of cancer may be treated by implanting seeds of different isotopes (for example, iodine or palladium) depending on its biological characteristics. Further, depending on the size of the tumor, the number of implanted seeds that may be required to effectively treat the cancer is quite variable (for example, from 25 to 100 seeds). In addition, implantable seeds may be manufactured with different amounts of radioactivity, and it may be preferable to implant fewer seeds with higher activity in some cases while in other cases it may be preferable to implant a larger number of seeds with lower activity. To further complicate the matter, the HCPCS codes used to report implantation of brachytherapy seeds are not tumor-specific. Instead, they are defined based on the number of sources, that is, the number of seeds or ribbons used in the procedure. This means that the treatment of many different tumors requiring implantation of widely varying numbers of seeds is described by a single HCPCS code. Therefore, it has been argued that given the costs of seeds and the variety of treatments described by a single HCPCS code, the cost of brachytherapy billed under a single HCPCS code could vary by as much as \$3,000.

In determining whether to package seeds into their associated procedures, we considered all these factors as well as our claims data. Consistent with our proposed policy for other device costs and the cost of many drugs, as well as with the principles of a prospective payment system, our preferred policy is to package the cost of brachytherapy devices into their associated procedures. For 2003, in the case of remote afterloading high intensity brachytherapy and prostate brachytherapy, which we discuss below, we propose to package the costs into payment for the procedures with which they are billed.

For other uses of brachytherapy, we propose to defer packaging of brachytherapy seeds for at least 1 year. In those cases, when paying separately in 2003 for brachytherapy seeds, we propose to continue payment on a per seed basis. The payment amount would be based on the median cost of brachytherapy seeds, per seed, as determined from our claims data.

We solicit comments on methodologies we might use to package all brachytherapy seeds beginning in CY 2004. For example, creation of tumor-specific brachytherapy HCPCS codes would reduce the variability in seed implantation costs associated with the current HCPCS codes used for seed implantation.

As stated above, beginning January 1, 2003, we propose to package payment for brachytherapy seeds into the payment for the following two types of brachytherapy services:

Remote Afterloading High Intensity Brachytherapy.

Participants in the April 5, 2002 Town Hall meeting expressed concern about packaging single use brachytherapy seeds into payment for procedures.

Remote afterloading high intensity brachytherapy treatment does not involve implantation of seeds. Instead, it utilizes a single radioactive "source" of high dose iridium with a 90-day life span. This single source is purchased and used multiple times in multiple patients over its life. One or more temporary catheters are inserted into the area requiring treatment, and the radioactive source is briefly inserted into each catheter and then removed. Because the source never comes in direct contact with the patient, it may be used for multiple patients. We note that the cost of the radioactive source, per procedure, is the same irrespective of how many catheters are inserted into the patient. Further, because the number of treatments administered with a single source over a 90-day period may vary and because the cost of the source is fixed, it is difficult if not impossible to determine a per "treatment" cost for the source. Moreover, we believe that

the costs of this type of source should be amortized over the life of the source. Therefore, each hospital administering this type of therapy should include a charge (which is hospital-specific) for the radiation source in the charge for the procedure. Therefore, we propose to package the costs associated with high dose iridium into the HCPCS codes used to describe this procedure. Those codes are: 77781, 77782, 77783, and 77784.

Prostate Brachytherapy.

The preponderance of brachytherapy claims under OPPS to date is for prostate brachytherapy. Brachytherapy is administered in several other organ systems, but the claims volume for non-prostate brachytherapy is very small, and hence our base of information on which to make payment decisions is slim. Furthermore, prostate brachytherapy uses only two isotopes, which are similar in cost, while brachytherapy on other organs involves a variety of isotopes with greater variation in cost. Consequently, we believe it would be prudent to wait for further experience to develop before proceeding to package non-prostate brachytherapy seeds.

A number of commenters at the April 5, 2002, Town Hall Meeting and elsewhere have stressed to us their views that brachytherapy seeds should remain unpackaged. The

principle argument put forth in favor of this approach is that the number of seeds used is highly variable across patients. We do not find this argument compelling. Payments in the OPSS, as in other prospective payment systems, are based on averages. We expect hospitals, in general, to be able to accommodate variation across patients in resource costs of services paid in a particular payment cell. The degree of variation should be immaterial as long as the payment is appropriate for a typical case, the hospital treats a caseload the resource use of which approximates a typical distribution, and the number of cases treated by a hospital is sufficiently large to overcome peculiarities in resource use that might be observed with a very small number of cases. We believe the service volume at hospitals providing prostate brachytherapy is likely to be large enough for a payment reflecting average use of seeds to be appropriate.

Additionally, appropriate payment for prostate brachytherapy has been of concern to many commenters since implementation of the OPSS because facilities must use multiple HCPCS codes on a single claim to accurately describe the entire procedure. Because we determine APC relative weights using single procedure claims, commenters have argued that payments for prostate brachytherapy are,

in part, based on error claims, resulting in underpayment for this important service. We agree that basing the relative weights for APCs reported for prostate brachytherapy services on only the small number of claims related to this service that are single procedure claims may be problematic. To increase the number of claims we could use to develop the proposed 2003 relative payment weights for prostate brachytherapy, we began by identifying all claims billed in 2001 for prostate brachytherapy. That is, we identified all claims that contained a line item for HCPCS code 77778, Interstitial radiation source application; complex, and HCPCS code 55859, Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy. We discovered more than 12,000 claims that met these specifications, suggesting that most of the procedures coded under HCPCS code 77778 were for prostate brachytherapy. Unfortunately, closer analysis of these claims revealed that hospitals do not report prostate brachytherapy using a uniform combination of codes. Of the more than 12,000 claims for prostate brachytherapy that we identified in the 2001 claims data, no single combination of HCPCS codes occurred more than 25 times.

Therefore, in order to facilitate tracking of this service, we propose to establish a G code for hospital use only that will specifically identify prostate brachytherapy. We propose as the descriptor for this G code the following: "Prostate brachytherapy, including transperineal placement of needles or catheters into the prostate, cystoscopy, and interstitial radiation source application." This G code would be used by hospitals instead of HCPCS codes 55859 and 77778 to bill for prostate brachytherapy. Hospitals would continue to use HCPCS codes 55859 and 77778 when reporting services other than prostate brachytherapy. We would also instruct hospitals to continue to report separately other services provided in conjunction with prostate brachytherapy, such as dosimetry and ultrasound guidance. These additional services would be paid according to the APC payment rate established by our usual methodology.

This G code will allow us to package brachytherapy seeds into the procedures for administering prostate brachytherapy while permitting us to pay separately for brachytherapy seeds which are administered for other procedures. Therefore, we propose to package the costs of the brachytherapy seeds, catheters, and needles into the payment for the prostate brachytherapy G code. In order to

develop a payment amount for this G code, we used all claims where both HCPCS codes 55859 and 77778 appeared. We packaged all revenue centers and appropriate HCPCS codes, that is, HCPCS with status indicator "N." We then determined median costs of the line items for HCPCS codes 55859 and 77778 and added the two. Next, we packaged the costs of all C codes, whether an item-specific or a device category code, into the payment amount. We propose to assign APC 0684 with status indicator "T." We believe the payment rate proposed for this G code appropriately reflects the costs of the procedures, the brachytherapy seeds, and any other devices associated with these procedures. We solicit comments on this proposal.

Packaging of Other Device Costs Associated with Brachytherapy

We propose to package the costs of brachytherapy needles and catheters with whichever procedures they are reported, similar to our proposal for packaging the costs of other devices that will no longer be eligible for a transitional pass-through payment in 2003. Because the HCPCS code descriptors for brachytherapy are based on the number of catheters or needles used, we believe the costs of these devices would be appropriately reflected within the costs of the associated procedure.

D. Criteria for New Device Categories

Section 1833(t)(6)(B)(ii) of the Act, as amended by BIPA, required us to establish criteria by July 1, 2001 that will be used to create additional device categories to be used in determining eligibility of a device for pass-through payments. This provision requires that no medical device be described by more than one category. In addition, the criteria must include a test of whether the average cost of devices that would be included in a category is "not insignificant" in relation to the APC payment amount for the associated service.

On November 2, 2001, we published in the **Federal Register** an interim final rule (66 FR 55850) that set forth

the criteria for establishing new (that is, additional) categories of medical devices eligible for transitional pass-through payments under the hospital outpatient PPS as required by section 1833(t)(6)(B)(ii) of the Act. The provisions relating to transitional pass-through payments for eligible drugs and biologicals remained unchanged and were not addressed in the November 2001 interim final rule (except for a change relating to contrast agents as provided in section 430 of BIPA). We received several public comments regarding our criteria published in the November 2001 interim final rule. We will respond to these public comments in the final rule for the OPSS for 2003.

In the November 2, 2001 interim final rule, we implemented new §419.66(c), which establishes the criteria for establishing a new device category. We propose to make a technical correction to §419.66(c)(1), which establishes one of those criteria. Specifically, we discuss in the November 2, 2001 interim final rule the criterion that a new category must describe devices that demonstrate substantial improvement in medical benefits for Medicare beneficiaries compared to the benefits obtained by devices in previously established (that is, previously existing) categories or other available treatments, as described in regulations at new §419.66(c)(1) (66 FR 55852). Section

1833(t) (6) (B) (ii) (IV) of the Act requires that a new category must include medical devices for which no existing category, or one previously in effect, is appropriate. In the November 2, 2001 IFC, we addressed in the preamble the requirement that no category previously in effect could describe a new category (66 FR 55852), but we did not conform the regulations text to this requirement.

Therefore, we propose to correct §419.66(c) (1) to read as follows:

(1) CMS determines that a device to be included in the category is not described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.

E. Payment for Transitional Pass-Through Drugs and Biologicals for Calendar Year 2003

As discussed in the November 13, 2000 interim final rule (65 FR 67809) and the November 30, 2001 final rule (66 FR 59895), we update the payment rates for pass-through drugs on an annual basis. Therefore, as we have done for prior updates, we propose to update the APC rates for drugs that are eligible for pass-through payments in 2003 using the most recent version of the Red Book, the July 2002 version in this case. The updated rates effective January

1, 2003 would remain in effect until we implement the next annual update in 2004, when we would again update the AWP for any pass-through drugs based on the latest quarterly version of the Red Book. This retains the update of pass-through drug prices on the same calendar year schedule as the other annual OPPS updates.

As described in our final rule of November 30, 2001 (66 FR 59894), in order to establish the applicable beneficiary copayment amount and the pass-through payment amount, we must determine the cost of the pass-through eligible drug or biological that would have been included in the payment rate for its associated APC had the drug or biological been packaged. We used hospital acquisition costs as a proxy for the amount that would have been packaged, based on data from an external survey of hospital drug costs (see the April 7, 2000 final rule (65 FR 18481)). That survey concluded that--

- For drugs available through only one source drugs, the ratio of acquisition cost to AWP equals 0.68;
- For multisource drugs, the ratio of acquisition cost to AWP equals 0.61;
- For drugs with generic competitors, the ratio is 0.43.

As we stated in our final rule of November 30, 2001 (66 FR 59896), we considered the use of the study-derived ratios of drug costs to AWP to be an interim measure until we could obtain data on hospital costs from claims. We stated that we anticipated having this data to use in setting payment rates for 2003.

As described elsewhere in this preamble, we used 2001 claims data to calculate a median cost per unit of drug for each drug for which we are currently paying separately. We compared the median per unit cost of each drug to the AWP to determine a ratio of acquisition cost to AWP. Using the total units billed for each drug, we then calculated a weighted average for each of the above three categories of drugs. These calculations resulted in the following weighted average ratios:

- For sole-source drugs, the ratio of cost to AWP equals 71.0 percent.
- For multisource drugs, the ratio of cost to AWP equals 68.0 percent.
- For drugs with generic competitors, the ratio of cost to AWP equals 46.0 percent.

We propose to use these percentages for determining the applicable beneficiary copayment amount and the pass-

through payment amount for drugs eligible for pass-through payment in 2003.

We propose to use these percentages for determining the applicable beneficiary copayment amount and the pass-through payment amount for most drugs eligible for pass-through payment in 2003. However some drugs may fall into two other classes. The first class includes a drug that is new and for which no cost is yet included in an associated APC. For such a drug, because there is no cost for the drug yet included in an associated APC, the pass-through amount will be 95 percent of the AWP and there would be no copayment. The second class includes a drug that is new and is a substitute for only one drug that is recognized in the OPPS through an unpackaged APC. For drugs in this second class, the pass-through amount would be the difference between 95 percent of the AWP for the pass-through drug and the payment rate for the comparable dose of the associated drug's APC. The copayment would be based on the payment rate of its associated APC. We believe that using this methodology will yield a more accurate payment rate.

We have received questions with respect to our definition of multisource drugs. In determining whether a drug is available from multiple sources, we consider

repackagers to be among the sources. This is consistent with the findings of the survey cited above which indicated a lower ratio of acquisition cost to AWP from multiple sources including repackagers.

We note that determining that a drug is eligible for a pass-through payment or assigning a status indicator "K" to a drug or biological (indicating that the drugs or biologicals is paid based on a separate APC rate) indicates only the method by which the drug or biological is paid if it is covered by the Medicare program. It does not represent a determination that the drug is covered by the Medicare program. For example, Medicare contractors must determine whether the drug or biological is: 1) reasonable and necessary to treat the beneficiary's conditions; and 2) excluded from payment because it is usually self-administered by the patient.

IV. Wage Index Changes for Calendar Year 2003

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

We used the proposed Federal fiscal year (FY) 2003 hospital inpatient PPS wage index to make wage adjustments

in determining the proposed payment rates set forth in this proposed rule. The proposed FY 2003 hospital inpatient wage index published in the May 9, 2002 **Federal Register** (67 FR 31431) is reprinted in this proposed rule as Addendum H--Wage Index for Urban Areas; Addendum I--Wage Index for Rural Areas; and Addendum J--Wage Index for Hospitals That Are Reclassified. We propose to use the final FY 2003 hospital inpatient wage index to calculate the payment rates and coinsurance amounts that we will publish in the final rule implementing the OPPS for CY 2003.

V. Copayment for Calendar Year 2003

Section 1833(t)(8)(C)(ii) of the Act accelerates the reduction of beneficiary copayment amounts, providing that, for services furnished on or after April 1, 2001 and before January 1, 2002, the national unadjusted coinsurance for an APC cannot exceed 57 percent of the APC payment rate. The statute provides that the national unadjusted coinsurance for an APC cannot exceed 55 percent in 2002 and 2003. The statute provides for further reductions in future years so that the national unadjusted coinsurance for an APC cannot exceed 55 percent of the APC payment rate in 2002 and 2003, 50 percent in 2004, 45 percent in 2005, and 40 percent in 2006 and thereafter.

For 2003, we determined copayment amounts for new and revised APCs using the same methodology that we implemented for 2002 (see the November 30, 2001 final at 66 FR 59888). See Addendum B for proposed national unadjusted copayments for 2003. Our regulations at \$419.41 conform to this provision of the Act.

VI. Conversion Factor Update for Calendar Year 2003

Section 1833(t)(3)(C)(ii) of the Act requires us to update the conversion factor used to determine payment rates under the OPPS on an annual basis.

Section 1833(t)(3)(C)(iv) of the Act provides that for 2003, the update is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act.

The most recent forecast of the hospital market basket increase for FY 2003 is 3.5 percent. To set the proposed OPPS conversion factor for 2003, we increased the 2002 conversion factor of \$50.904 (the figure from the March 1, 2002 final rule (67 FR 9556)) by 3.5 percent.

In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the proposed conversion factor for 2003 to ensure that the revisions we are proposing to update by means of the wage index are made on a budget-neutral basis. We calculated a budget neutrality factor of .98715 for wage

index changes by comparing total payments from our simulation model using the proposed FY 2003 hospital inpatient PPS wage index values to those payments using the current (FY 2002) wage index values.

The increase factor of 3.5 percent for 2003 and the required wage index budget neutrality adjustment of .98715 result in a proposed conversion factor for 2003 of 52.009.

VII. Outlier Policy for Calendar Year 2003

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

As explained in the April 7, 2000 final rule (65 FR 18498), we set a target for outlier payments at 2.0 percent of total payments. For purposes of simulating payments to calculate outlier thresholds, we propose to continue to set the target for outlier payments at 2.0 percent, as we did for CYs 2001 and 2002. For 2002, the

outlier threshold is met when costs of furnishing a service or procedure exceed 3.5 times the APC payment amount, and the current outlier payment percentage is 50 percent of the amount of costs in excess of the threshold. Based on our simulations for 2003, we propose to set the threshold for 2003 at 2.75 times the APC payment amounts, and the proposed 2003 payment percentage applicable to costs over the threshold at 50 percent.

VIII. Other Policy Decisions and Proposed Changes

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

Background

Currently, facilities code clinic and emergency department visits using the same current procedural terminology (CPT) codes as physicians. For both clinic and emergency department visits, there are five levels of care. While there is only one set of codes for emergency visits, clinic visits are differentiated by new patient, established patient, and consultation visits. CPT codes 99201 through 99205 are used for new patients, CPT codes 99211 through 99215 are used for established patients, and CPT codes 99281 through 99285 for emergency patients.

Physicians determine the proper code for reporting their services by referring to CPT descriptors and our

documentation guidelines. The descriptors and guidelines are helpful to physicians because they reference taking a history, performing an examination, and making medical decisions. The lower levels of service (for example, CPT codes 99201, 99211, and 99281) are used for shorter visits and for patients with uncomplicated problems, and the higher levels of service (for example, CPT codes 99205, 99215, and 99285) are used for longer visits and patients with complex problems.

These codes were defined to reflect the activities of physicians. It is generally agreed, however, that they do not describe well the range and mix of services provided by facilities to clinic and emergency patients (for example, ongoing nursing care, preparation for diagnostic tests, and patient education).

Before the implementation of the OPSS, facilities were paid on the basis of charges reduced to costs. In that system, because use of a correct HCPCS code did not influence payment, there was little incentive to correctly report the level of service. In fact, many facilities reported all clinic and emergency visits with the lowest level of service (for example, CPT codes 99211, 99201, and 99281) simply to minimize administrative burden (for

example, charge-masters might include only one level of service).

This situation changed with the implementation of the OPSS. The OPSS requires correct reporting of services using HCPCS codes as a prerequisite to payment. For emergency and clinic visits, the OPSS distinguishes three levels of service for payment purposes. These are referred to as "low-level," "mid-level," and "high-level" emergency or clinic visits. Low-level clinic and emergency visits include CPT codes for level one and two services (for example, CPT codes 99201, 99211, and 99281), mid-level visits include level three services (for example, CPT codes 99203, 99213, and 99283), and high-level visits include level four and five services (for example, CPT codes 99205, 99215, and 99285). Payment rates for low-level visits are less than for mid-level visits, which are less than rates for high-level visits.

In the April 7, 2000 final rule (65 FR 18434), we stated that to pay hospitals properly, it was important that emergency and clinic visits be coded properly. To facilitate proper coding, we required each hospital to create an internal set of guidelines to determine what level of visit to report for each patient. We stated in the rule, that if hospitals set up these guidelines and

follow them, they would be in compliance with OPPS coding requirements for the visits. Furthermore, we announced that we would be reviewing this issue and planned to set national guidelines for coding clinic and emergency visits in the future. In the August 24, 2001 proposed rule (66 FR 44672), we asked for public comments regarding national guidelines for hospital coding of emergency and clinic visits. We also announced that we would compile these comments and present them to our APC Panel at the January 2002 meeting. We also announced that we planned to propose uniform national facility coding guidelines in the proposed rule for the 2003 OPPS.

During its January 2002 meeting, the APC Panel reviewed written comments, heard oral testimony, discussed the issue, and made recommendations concerning establishment of facility coding guidelines for emergency and clinic visits. Among those who submitted oral and written comments to us and to the Panel were national hospital organizations, national physician organizations, hospital systems, individual hospitals, coding organizations, and consultants.

Discussion

We set forth below, by issue, a summary of the comments we received:

- **The need for national coding guidelines.**

Except for the American Medical Association (AMA) and one other physician organization, commenters unanimously agreed that national guidelines for facility coding of emergency and clinic visits were required. Furthermore, most commenters requested that we establish these guidelines as soon as possible, but, in any event, not later than January 2003. Among the reasons cited were the following:

- + The need for facilities to comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA), no later than October 16, 2003 (October 16, 2002 for those entities that do not obtain a one-year extension). Commenters expressed concern that use of CPT E/M codes with different reporting rules when used by facilities (as opposed to use by physicians) would violate HIPAA requirements.

- + The need for facilities to set up effective audit and compliance programs.

- + The need to minimize confusion on the part of coders.

- + The need to minimize inaccurate payments.

- + The need to prevent gaming of the system by facilities.

The AMA recommended that we wait for the CPT Editorial Panel to develop coding guidelines for hospitals to assure that coding guidelines will be minimally burdensome to hospitals.

- **The need to establish principles against which facility E/M coding guidelines would be measured.**

Commenters unanimously agreed that any set of coding guidelines for facilities would have to satisfy a uniform set of basic principles to be acceptable to, and accepted by, hospitals. These include the following:

- + Coding guidelines for emergency and clinic visits should be based on emergency department or clinic facility resource use, not physician resource use.

- + Coding guidelines should be clear, facilitate accurate payment, be usable for compliance purposes and audits, and meet HIPAA requirements.

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

- + Coding guidelines should not facilitate upcoding or gaming.

We would add one other requirement to these principles: The distribution of codes should result in a

normal curve. Documentation guidelines should facilitate this result.

- **Current use of hospital coding guidelines is inconsistent and much more prevalent in the emergency department.**

Several commenters noted that many hospitals have developed their own coding guidelines but that no specific set of guidelines is in widespread use at the present time. These commenters noted that guidelines have been used much more in the emergency department setting than in the clinic setting. They also noted that only one set of guidelines has undergone any sort of testing. These are the facility coding guidelines for emergency departments, developed and copyrighted by the American College of Emergency Physicians (ACEP). Unfortunately, the testing was not done by protocol, no quantitative data were collected, and only a small number of facilities participated.

- **Development of two sets of guidelines: one for emergency department visits and one for clinic visits.**

Several commenters noted that the types and intensity of hospital resources used for emergency department visits were significantly different from the types and intensity of resources used for clinic visits. These commenters

recommended that we adopt different guidelines for emergency department and clinic visits.

- **The need to develop new descriptors and codes for facility emergency and clinic visits.**

Commenters unanimously agreed that the current CPT descriptors for E/M services were not only inappropriate for facility coding of emergency and clinic visits but also were confusing and misleading to both facility coders and our reviewers. Commenters stated that patients whose complexity level was low in terms of physician work could frequently require highly intensive and complex facility services (for example, patients with gastroenteritis who require intravenous fluids, patients in motor vehicle accidents who require multiple X-rays, or patients with congestive heart failure or diabetes who require extensive education). In these cases, lack of agreement between physician and hospital coding would be clinically appropriate but could be the source of an investigation given the current code descriptors and hospital reporting guidelines. Commenters were also concerned that internal hospital-specific coding guidelines could vary greatly because the current CPT descriptors exclude any reference to facility services and, therefore, are highly susceptible to individual interpretation. A third concern was HIPAA

compliance. Commenters believe that development by individual hospitals of a second set of descriptors that the hospital uses when reporting E/M codes could violate HIPAA requirements. These commenters believe that when HIPAA is first implemented on October 16, 2002 (October 16, 2003 for those entities that obtain a one-year extension), Healthcare Common Procedure Coding System (HCPCS) codes must be used uniformly by all providers. Two sets of descriptors for a single set of codes would require that different providers (that is, physicians and hospitals) use the codes differently. Based on these concerns, all commenters recommended that we develop, on an interim basis, HCPCS codes for emergency and clinic visits with descriptors specific for hospital coding.

- **Maintenance of five levels of service.**

Although a few commenters were not certain that facilities needed to differentiate among five levels of service, they believe that reducing the number of levels of service, even if clinically appropriate, would cause significant confusion among coders and reviewers. Therefore, they recommended maintaining five levels of service on an interim basis until more data on this issue can be obtained.

- **Recommendations concerning adoption of specific guidelines.**

Commenters recommended four basic types of guidelines for adoption.

1. Guidelines based on the number or type of staff

interventions. Under this model, the level of service reported would be based on the number and/or type of interventions performed by nursing or ancillary staff. In the intervention model, baseline care (including registration, triage, initial nursing assessment, periodic vital signs as appropriate, simple discharge instructions, and exam room set up/clean up) and possibly a single minor intervention (for example, suture removal, rapid strep test, visual acuity) would be reported by the lowest level of service. Higher levels of service would be reported as the number and/or complexity of staff interventions increased.

The most commonly recommended intervention-based guidelines were the facility-coding guidelines developed by ACEP. The ACEP model uses examples of interventions to illustrate appropriate coding. Coders extrapolate from these examples to determine the correct level of service to report. The ACEP model uses the type of intervention rather than the number of interventions to determine the

appropriate level of service. This means that the single most complex intervention determines the level of service whether it was the only service provided (in addition to baseline care), whether other similarly complex interventions were also provided, or whether other interventions of less complexity were also provided. The intervention model is based on emergency/clinic resource use, is simple, reflects the care given to the patient, and does not require additional facility documentation.

However, we are concerned that the intervention model may provide an incentive to provide unnecessary services and that it is susceptible to upcoding. Furthermore, the ACEP model requires extrapolation from a set of examples that could make it prone to variability across hospitals.

2. Guidelines based on the time staff spent with the patient. Under this model, the level of service would be determined based on the amount of time hospital staff spent with the patient. The underlying assumption is that staff time spent with the patient is an appropriate proxy for total facility resource consumption. In this model, if only baseline care (as described above) were provided a Level 1 service would be reported. Higher levels of service would be reported based on increments of staff time beyond baseline care (for example, Level 2 would be

reported for 11 to 20 minutes beyond baseline care, and Level 3 would be reported for 21 to 30 minutes beyond baseline care). This model is simple, it correlates with total facility resource use, and it would provide an objective standard for all hospitals to follow. However, extra, potentially burdensome, documentation (that is, documentation of staff time that is not normally required for clinical care) would be necessary, there would be an incentive to work slowly or use less efficient personnel, and there would be significant potential for upcoding and gaming.

3. Guidelines based on a point system where a certain number of points is assigned to each staff intervention based on the time, intensity, and staff type required for the intervention. In this model, points or weights are assigned to each facility service and/or intervention provided to a patient in the clinic or emergency department. The level of service is determined by the sum of the points for all services/interventions provided. Commenters recommended various approaches to a point system including point systems that assigned points based on the amount of staff time spent with the patient, the number of activities performed during the emergency department or clinic visit, and a combination of patient condition and

activities performed. A point system would correlate with facility resource consumption and provide an objective standard. However, a point system could present significant burdens for hospitals in terms of requiring extra, clinically unnecessary, documentation. Point systems are extremely complex, would probably require dedicated staff to monitor and maintain, and would be susceptible to upcoding and gaming.

4. **Guidelines based on patient complexity.** Several variations were recommended including assignment of level of service based on ICD-9-CM (International Classification of Diseases, Ninth Edition, Clinical Modification) diagnosis codes, assignment of level of service based on complexity of medical decision making, or assignment of level of service based on presenting complaint or medical problem. The premise for these systems is that many emergency departments follow established protocols based on patients presenting complaints and diagnoses. Therefore, assigning a level of service based on patient diagnosis should correlate with facility resource consumption. These systems require the use of a coding "grid," which lists more than 100 examples of patient conditions and diagnosis and assigns a level of service to each example. When a patient has a condition that does not appear on the grid,

the coder must extrapolate from the grid to the individual patient. These systems are extremely complex, demand significant interpretive work on the part of a coder (who may not have clinical experience), and are subject to variability across hospitals. No clinically unnecessary documentation would be required but, because the system is based on diagnosis, there is a significant potential for upcoding and gaming.

APC Panel Recommendations

The APC Panel reviewed the comments that we received, reviewed background material we prepared, and heard oral testimony. Most commenters recommended that we adopt the ACEP guidelines. However, one organization representing cancer centers stated that the most appropriate proxy for facility resource consumption in cancer care is staff time and asked that we consider basing our guidelines on staff time. Commenters agreed that we needed to address this problem in the proposed rule for CY 2003. They also agreed that to address potential HIPAA compliance issues, we should develop new HCPCS codes for facility visits; and that we should maintain five levels of service for emergency and clinic visits until data are available to show that only three levels of service are required to ensure accurate payments. Commenters also agreed that, for

the same level of service, clinic resource consumption should be similar for new, established, and consultation patients. Therefore, we need only create a single set of five codes for clinic visits.

After a thorough discussion, the APC technical panel made the following recommendations:

1. Propose and make final facility coding guidelines for E/M services for calendar year 2003.
2. Create a series of G codes with appropriate descriptors for facility E/M services.
3. Maintain a single set of codes, with five levels of service, for emergency department visits.
4. Develop a single set of codes, with five levels of service, for clinic visits. The Panel specifically recommended that we not differentiate among visit types (for example, new, established, and consultation visits) for the purposes of facility coding of clinic visits.
5. Adopt the ACEP facility coding guidelines as the national guidelines for facility coding of emergency department visits.
6. Develop guidelines for clinic visits that are modeled on the ACEP guidelines but are appropriate for clinic visits.

7. Implement these guidelines as interim and continue to work with appropriate organizations and stakeholders to develop final guidelines.

Proposal

We have reviewed the written comments, the oral testimony before the APC Panel, and the Panel's recommendations. We agree that facility coding guidelines should be implemented as soon as possible. We are particularly concerned that facilities be able to comply with HIPAA requirements. We have worked, and will continue to work, on this issue, with hospitals, organizations representing hospitals, physicians, and organizations representing physicians. We note that the AMA CPT Editorial Panel is not currently considering the issue of facility coding guidelines for clinic visits and that the earliest any CPT guidelines could be implemented would be in January 2004. Additionally, consistent with the intent of the outpatient prospective payment system, we want to ensure that reporting of hospital emergency and clinic visits is resource based.

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

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

With regard to the documentation guidelines, our primary concerns are to make appropriate payment for medically necessary care, to minimize the information collection and reporting burden on facilities, and to minimize any incentive to provide unnecessary or low quality care. We realize that many facilities use complaint or diagnosis driven care protocols and that current documentation standards do not include

documentation of staff time or the complexity of diagnostic and therapeutic services provided. Therefore, in the interest of facilitating the delivery of medically necessary care in a clinically appropriate way, we believe that the potential drawbacks of each of the recommended sets of guidelines outweigh the potential benefits of creating uniformity and reproducibility. For example, any documentation system requiring counting or quantification of resource use has the potential to be burdensome, require clinically unnecessary documentation, and be susceptible to upcoding and gaming. Documentation systems using coding grids or a series of clinical examples for each level of service are subject to interpretation, may induce variability, may be overly complex and burdensome, and may result in disagreements with medical reviewers. We are also concerned that all the proposed guidelines allow counting of separately paid services (for example, intravenous infusion, x-ray, EKG, lab tests, etc.) as "interventions" or "staff time" in determining a level of service. We believe that, within the constraints of clinical care and management protocols, the level of service for emergency and clinic visits should be determined by resource consumption that is not otherwise separately payable.

To address these concerns, in addition to reviewing written comments, oral comments, and the APC Panel recommendations, we have also reviewed the current distribution of paid emergency and clinic visit codes in the OPPS. With regard to emergency visits, we have observed that well over 50 percent of the visits are considered "multiple procedure claims" because the claim includes services such as diagnostic tests (for example, EKGs, x-rays) or therapeutic interventions (for example, intravenous infusions). The distribution of all emergency services is in a bell-shaped curve with a slight left shift because there are more claims for CPT codes 99281 and 99282 than for CPT codes 99284 and 99285. This pattern of coding is significantly different from physician billing for emergency services, which is skewed and peaks at CPT code 99284. We also note that the median costs for successive levels of emergency visits show an expected increase across APCs.

With regard to clinic visits, we have observed that more than 50 percent of the services are considered "single claims" meaning that they are billed without any other significant procedures such as diagnostic tests or therapeutic interventions. We also note that the distribution of clinic visits is skewed with the majority

being low-level clinic visits. This distribution is consistent with pre-OPPS billing patterns where many facilities billed all clinic visits as low level visits. However, the median costs for different levels of clinic services, while similar within an APC, do not show the expected increase across the clinic visit APCs.

Based on our review, on the current distribution of coding for emergency and clinic visits, and on our understanding that hospitals set charges for services based on the resources used to provide those services, we believe that an incremental approach to developing and implementing documentation guidelines for emergency and clinic visits is appropriate. As hospitals become more familiar with the OPPS and with the need to differentiate emergency and clinic visits based on resource consumption, we will continue to review the advantages and disadvantages of detailed, uniform documentation guidelines. We plan to begin the development of uniform guidelines over the next year. If we are ready, we would propose the guidelines for comments in our Federal Register document for the calendar year 2004 update. For calendar year 2003, we propose the following new codes:

Emergency Visits

Our data indicate that, in general, hospitals under the OPPS are reporting emergency visits appropriately. We believe that insofar as hospitals have existing guidelines for determining the level of emergency service, those guidelines reflect facility resource consumption. Therefore, we propose that GXXX1 - Level 1 Facility Emergency Services be reported when facilities deliver, and document, basic emergency department services. These services include registration, triage, initial nursing assessment, minimal monitoring in the emergency department (for example, one additional set of vital signs), minimal diagnostic and therapeutic services (for example, rapid strep test, urine dipstick), nursing discharge (including brief home instructions), and exam room set up/clean up. We would expect that these services would be delivered to patients who present with minor problems of low acuity.

With regard to GXXX2 through GXXX5, we propose to require that facilities develop internal documentation guidelines based on hospital resource consumption (for example, staff time). These guidelines must be appropriate for the type of services provided in the hospital and must also clearly differentiate the relative resource consumption for each level of service so that a medical

reviewer can easily infer the type, complexity, and medical necessity of the services provided and validate the level of service reported. Because there is great variability in available facility resources, staff, and clinical protocols among facilities, we do not believe that it is advisable to require a single set of guidelines for all facilities. Instead, we believe it is appropriate for each facility to develop its own documentation guidelines that take into account the facility's clinical protocols, available facility resources, and staff types. As stated above, we are not proposing any specific requirements with regard to the basis of these guidelines. However, the guidelines must be tied to actual resource consumption in the emergency department such as number and type of staff interventions, staff time, clinical examples, or patient acuity. We also propose to require that facilities have documentation guidelines available for review upon request. The guidelines must emphasize relative resource consumption and must not, to the extent possible, set minimal requirements as a basis for determining the level of service (for example, require 30 minutes of staff time or five staff interventions to bill a Level 3 emergency visit).

If made final, these requirements would be interim. We will work with interested parties to revise these requirements and would propose any revision to these requirements in a future proposed rule.

Clinic Visits

The current distribution of codes for clinic visits may be due to a facility's continued use of pre-OPPS coding policies for clinic visits. We believe that over time facilities will become as experienced differentiating levels of clinic visits as they are at differentiating levels of emergency visits. Therefore, we propose a set of guidelines for clinic visits that parallels the requirements for emergency visits. We propose that GXXX6 - Level 1 Facility Clinic Services, be reported when facilities deliver, and document, basic clinic services. These services include registration, triage, initial nursing assessment, minimal monitoring in the clinic (for example, one additional set of vital signs), minimal diagnostic and therapeutic services (for example, rapid strep test, urine dipstick), nursing discharge (including brief home instructions), and exam room set up/clean up. Our proposal for GXXX7 through GXXX10 is the same as for GXXX2 through GXXX5 except that the facility-specific guidelines must be tied to actual resource consumption in

the clinic such as number and type of staff intervention, staff time, clinical examples, or patient acuity. The guidelines must also differentiate the relative resource consumption in the clinic for each level of service sufficiently so that a medical reviewer could easily infer the type, complexity, and medical necessity of the services provided to validate the level of service provided.

This proposal, if made final, would also be interim while we work with interested parties to revise the requirements. Any revision would be proposed in a future proposed rule.

We propose to make final, in the 2003 OPPS final rule, changes in coding for clinic and emergency department visits and requirements related to the development of documentation guidelines for the new codes. However, we propose to implement the new codes and documentation guidelines no earlier than January 1, 2004. This will give hospitals time to develop documentation guidelines for the new codes and prepare their internal billing systems to accommodate the changes. We will continue to work with hospitals throughout CY 2003 as they develop the documentation guidelines. We solicit comments on this proposal overall as well as the specific components of the proposal.

B. Observation Services**Coding and Billing Instructions**

On November 30, 2001, we published a final rule updating changes to the OPPS for 2002. We implemented provisions that allow separate payment for observation services under certain conditions. That is, a hospital may bill for a separate APC payment (APC 0339) for observation services for patients with diagnoses of chest pain, asthma, or congestive heart failure when certain criteria are met. The criteria discussed in the November 30, 2001 final rule and as corrected in the March 1, 2002 final rule are also explained in detail in section XI of a Program Memorandum to intermediaries issued on March 28, 2002 (Transmittal A-02-026). Payment for HCPCS code G0244, observation care provided by a facility to a patient with congestive heart failure, chest pain or asthma, minimum eight hours, maximum 48 hours, was effective for services furnished on or after April 1, 2002.

Section XI of Transmittal A-02-026 that was issued on March 28, 2002 provides additional billing and coding instructions and requirements that flow from the basic criteria that we implemented in the November 30, 2001 and the March 1, 2002 final rules. Although we do not address them explicitly in the final rules, the additional

instructions and requirements in Transmittal A-02-026 were developed to implement the basic observation criteria within the programming logic of the outpatient code editor (OCE), which is used to process claims submitted by hospitals for payment under the OPSS. For example, in the November 30, 2001 final rule, we state that an emergency department visit (APC 0610, 0611, or 0612) or a clinic visit (APC 0600, 0601, or 0602) must be billed in conjunction with each bill for observation services (66 FR 59879). In section XI of Transmittal A-02-026, we state that an Evaluation and Management (E/M) code (referred to, incorrectly, in Transmittal A-02-026 as an "Emergency Management" code), for the emergency room, clinic visit, or critical care is required to be billed on the day before or the day that the patient is admitted to observation. That is, unless one of the CPT codes assigned to APCs 0600, 0601, 0602, 0610, 0611, 0612, or 0620 is billed on the day before or the day that the patient is admitted to observation, separate payment for G0244 is not allowed. The codes assigned to these APCs are categorized by CPT as E/M codes. Although we did not include APC 0620, Critical Care, among the APCs that must be billed in order to receive separate payment for observation services, we added it in the program memorandum because critical care is

an E/M service which can be furnished in a clinic or an emergency department. Critical care may appropriately precede admission to observation for chest pain, asthma, or congestive heart failure. We clarify in Transmittal A-02-026 that both the associated E/M code and G0244 are paid separately if the observation criteria are met. We also specify that the E/M code associated with observation must be billed on the same claim as the observation service.

Similarly, in the November 30, 2001 and the March 1, 2002 final rules, we require that certain diagnostic tests be performed in order to bill for separate payment for observation services. In Transmittal A-02-026, in section XI.B.2, we list the diagnostic tests that the OCE looks for on a bill for G0244. This list, which amplifies what we published in the November 30, 2001 and March 1, 2002 final rules, is incomplete and should read as follows to reflect the current OCE logic that is applied to claims for G0244:

- For chest pain, at least two sets of cardiac enzymes [either two CPK (82550, 82552, or 82553), or two troponin (84484 or 84512)], and two sequential electrocardiograms (93005);

- For asthma, a peak expiratory flow rate (94010) or pulse oximetry (94760, 94761, or 94762);

- For congestive heart failure, a chest x-ray (71010, 71020, or 71030) and an electrocardiogram (93005) and pulse oximetry (94760, 94761, or 94762).

- NOTE: Pulse oximetry codes 94760, 94761, and 94762 are treated as packaged services under the OPPS. Although as packaged codes no separate payment is made for these codes, hospitals must separately report the HCPCS code and a charge for pulse oximetry in order to establish that observation services for congestive heart failure and asthma diagnoses meet the criteria for separate payment.

Transmittal A-02-026 also provides specific coding instructions that hospitals must use when billing for observation services that do not meet the criteria for separate payment under APC 0339. In addition, Transmittal A-02-026 addresses the use of modifier -25 with the E/M code billed with G0244.

Direct Admissions to Observation

Since implementation of the provision for separate payment for observation services under APC 0339, a number of hospitals, hospital associations, and other interested parties have asked if separate payment for observation services would be allowed for a patient with chest pain, asthma, or congestive heart failure who is admitted directly into observation by order of the patient's

physician but without having received critical care or E/M services in a hospital clinic or the emergency department on the day before or the day of admission to observation. We have responded during monthly CMS hospital open forum calls that, consistent with the criteria in the November 30, 2001 final rule, effective for services furnished on or after April 1, 2002, separate payment for observation services requires that an admission to observation be made by order of a physician in a hospital clinic or in a hospital emergency department. If a patient is directly admitted to observation but without an associated E/M service (including critical care) shown on the same bill, the hospital should bill observation services using revenue code 762 alone or revenue code 762 with one of the HCPCS codes for packaged observation services (CPT codes 99218, 99219, 99220, 99234, 99235, or 99236).

A related question has arisen in connection with a policy interpretation that was posted as a response to a "Frequently Asked Question" (FAQ) on our web site on September 12, 2000. The FAQ follows:

"Q.97: If a patient is admitted from the physician's office to the observation room, will there be no reimbursement?"

"A.97: Since observation is a packaged service, payment cannot be made if it is the only OPPS service on a claim. However, we believe that the "admission" of a patient to observation involves a low-level visit billed by the hospital, as well as whatever office visit the physician who arranged for the admission billed. Thus, when a patient arrives for observation arranged for by a physician in the community (that is, "direct admit to observation"), and is not seen or assessed by a hospital-based physician, the hospital may bill a low-level visit code. This low-level visit code will capture the baseline nursing assessment, the creation of a medical record, the recording and initiation of telephone orders, etc. This visit may be coded only once during the period of observation. The observation charges should be shown in revenue code 762. The number of hours the patient was in observation status should be shown in the units field. Payment for those services is packaged into the APC for the visit. Other services performed in connection with observation, such as lab, radiology, etc., should be billed for as well"

We have been asked to clarify whether or not the low-level visit code suggested in the FAQ for patients directly admitted for observation services would satisfy the

requirement that a line item for a hospital emergency visit, hospital clinic visit, or critical care appear on the same bill as HCPCS code G0244. Our response is that when we established the final criteria effective for services furnished on or after April 1, 2002, we did not contemplate that the low-level visit described in the FAQ would satisfy the requirement for the E/M code that a hospital must bill to show a hospital clinic visit or hospital emergency department visit was performed before observation services for asthma, congestive heart failure, or chest pain to bill and receive payment for G0244 under APC 0339.

In light of these questions, we have reviewed the criteria for separate payment for observation services under APC 0339, and we propose to modify the criteria and coding for observation services furnished on or after January 1, 2003. Specifically, we propose to create two new codes. These additional codes would allow us to collect data on the extent to which patients are directly admitted to hospital observation services without an associated hospital clinic visit or emergency department visit. The proposed codes are as follows:

G0LLL—Initial nursing assessment of patient directly admitted to observation with diagnosis of congestive heart failure, chest pain, or asthma.

G0MMM—Initial nursing assessment of patient directly admitted to observation with diagnosis other than congestive heart failure, chest pain, or asthma.

If a hospital directly admits to observation from a physician's office a patient with a diagnosis of congestive heart failure, asthma, or chest pain, we propose to require that G0LLL be billed with G0244. The current requirement that the hospital bill an emergency department visit (APC 0600, 0601, or 0602) or a clinic visit (APC 0610, 0611, or 0612) or a critical care service (APC 0620) in order to receive separate payment for observation services for patients not admitted directly from a physician's office would remain in effect. However, because the initial nursing assessment is part of any observation service, we propose not to make separate payment for G0LLL. Rather, we propose to assign status indicator "N" to G0LLL, to designate that charges submitted with G0LLL would be packaged into the costs associated with APC 0339. If G0LLL is billed, we would require that the medical record show that the patient was admitted directly from a physician's

office for purposes of evaluating and treating chest pain, asthma, or congestive heart failure.

GOMMM describes the initial nursing assessment of a patient directly admitted to observation with a diagnosis other than chest pain, asthma, or congestive heart failure. We propose to assign GOMMM for payment under APC 0706, New Technology - Level I. We propose to require hospitals to bill GOMMM instead of the low level clinic visit referred to in the FAQ above to describe the initial nursing assessment of a patient directly admitted to observation with a diagnosis other than chest pain, asthma, or congestive heart failure. Separate payment would not be made for observation services billed with GOMMM. Rather, when billing GOMMM, hospitals would be required to use revenue code 762 alone or revenue code 762 with one of the HCPCS codes for packaged observation services (99218, 99219, 99220, 99234, 992335, or 99236). We propose to create GOMMM to establish a separately payable code into which costs for observation care for patients directly admitted for diagnoses other than asthma, chest pain, or congestive heart failure can be packaged and recognized.

We would use billing data for G0LLL and GOMMM in reviewing the provisions for payment of observation services in future updates of the OPSS. We invite comment

on the extent to which these codes address the concerns that have been raised in connection with patients who are directly admitted to observation services.

Billing Intravenous Infusions with Observation

Based on questions and concerns raised by hospitals since implementation of payment for APC 0339 effective April 1, 2002, we have also reviewed the current status of billing intravenous infusions with observation. Several hospitals have noted that claims for G0244 when billed with intravenous infusion services reported with HCPCS code Q0084 are denied because of the "T" status indicator assigned to HCPCS code Q0084. Our current payment rules for G0244 require that G0244 be denied if a service with status indicator "T" is performed the day before, the day of, or the day after observation care. Because patients in observation may require intravenous infusions of fluid, we propose to create code G0EEE, Intravenous infusion during separately payable observation stay, per observation, payable under APC 0340 with status indicator "X." When observation services that otherwise meet the billing requirements for separate payment under APC 0339 include an intravenous infusion administered as part of the observation care, G0EEE would be used to report the infusion service. We include instructions on the use of

G0EEE in the program memorandum issued to implement OPSS coding changes for the October 1, 2002 OCE. We solicit comment on the use of this code.

We discuss this and other new Level II HCPCS codes proposed for payment under the OPSS in section II.B.3 of this preamble. We instruct hospitals to use G0EEE only when billing for payment under APC 0339. G0EEE includes placement of the IV access and should not be billed with CPT code 36000.

Annual Update of ICD-9 Diagnosis Codes

To receive payment for G0244, we require hospitals to bill specified ICD-9-CM diagnosis code(s). Because ICD-9-CM codes are updated effective October 1 of each year, we propose to issue by Program Memorandum any changes in the diagnosis codes required for payment of G0244 resulting from the ICD-9-CM annual update.

In the March 1, 2002 final rule (67 FR 9559) and in Transmittal A-02-026 issued on March 28, 2002, we listed the diagnosis codes required in order for separate payment of observation services under APC 0339 to be made for patients with congestive heart failure. We added by program memorandum the following new ICD-9-CM codes to the list of allowed diagnosis codes for separate payment for observation of patients with congestive heart failure,

effective for services furnished on or after October 1, 2002:

- 428.20 unspecified systolic heart failure
- 428.21 acute systolic heart failure
- 428.22 chronic systolic heart failure
- 428.23 acute on chronic systolic heart failure
- 428.30 unspecified diastolic heart failure
- 428.31 acute diastolic heart failure
- 428.32 chronic diastolic heart failure
- 428.33 acute on chronic diastolic heart failure
- 428.40 unspecified combined systolic and diastolic heart failure
- 428.41 acute combined systolic and diastolic heart failure
- 428.42 chronic combined systolic and diastolic heart failure
- 428.43 acute on chronic combined systolic and diastolic heart failure

We invite comment on the addition of these diagnosis codes to the criteria for separate payment for observation services under APC 0339.

C. Payment Policy When a Surgical Procedure on the Inpatient List Is Performed on an Emergency Basis

As we state in section II.B.5 of this preamble, the inpatient list specifies those services that are only paid when provided in an inpatient setting. The inpatient list proposed for 2003 is printed as Addendum E. In Addendum B, status indicator C designates a HCPCS code that is on the inpatient list.

Over the past year, some hospitals and hospital associations have asked how a hospital could receive Medicare payment for a procedure on the inpatient list that had to be performed to resuscitate or stabilize a patient with an emergent, life-threatening condition who was transferred or died before being admitted as an inpatient. We reviewed within the context of our current policy the cases brought to our attention for which payment under the OPPS was denied because a procedure with status indicator C was on the bill. Based on that review, we propose to clarify our policy regarding Medicare payment when a procedure with status indicator C is performed under certain life-threatening, emergent conditions. We solicit comments on the extent to which the payment policy described below addresses hospitals' concerns. These comments would be most helpful if they are supported by specific examples of cases when hospitals have, in these

instances, submitted bills for a procedure with OPPS status indicator C that were not paid.

1. Current Policy

In the April 7, 2000 final rule (65 FR 18451), in response to comments about the appropriate level of payment for patients who die in the emergency department, we set forth the following guidelines for fiscal intermediaries to use in determining how to make payment when a patient dies in the emergency department or is sent directly to surgery and dies there.

- If the patient dies in the emergency department, make payment under the outpatient PPS for services furnished.
- If the emergency department or other physician orders the patient to the operating room for a surgical procedure, and the patient dies in surgery, payment will be made based on the status of the patient. If the patient had been admitted as an inpatient, pay under the hospital inpatient PPS (a DRG-based payment).
- If the patient was not admitted as an inpatient, pay under the outpatient PPS (an APC-based payment).
- If the patient was not admitted as an inpatient and the procedure is designated as an inpatient-only procedure

(payment status indicator C), no Medicare payment will be made for the procedure, but payment will be made for emergency department services.

The OPPS outpatient code editor (OCE) currently has an edit in place that generates a "line item denial" for a line on a claim that has a status indicator C. A line item denial means that the claim can be processed for payment but with some line items denied for payment. A line item denial can be appealed under the provisions of section 1869 of the Act. The OCE includes another edit that denies all other line items furnished on the same day as a line item with a status indicator C. The rationale for this edit is that all line items for services furnished on the same date as the procedure with status indicator C would be considered inpatient services and paid under the appropriate DRG.

As part of the definition of line item denial in the program memorandum that we issue quarterly to update the OCE specifications (for example, see Program Memorandum/Intermediaries, Transmittal A-02-052, June 18, 2002, which is available on our website at <http://www.hcfa.gov/pubforms/transmit/A02052.pdf>), we state that a line item denial cannot be resubmitted except for an

emergency room visit in which a patient dies during a procedure that is categorized as an inpatient procedure: "Under such circumstances, the claim can be resubmitted as an inpatient claim."

In Addendum D of the March 1, 2002 final rule, we designate payment status indicator "C" as follows: "Admit patient; bill as inpatient."

2. Hospital Concerns

Hospitals have requested clarification regarding billing and payment in certain situations that our current policy does not seem to explicitly address. The following scenarios synthesize cases described by hospitals for which they have encountered problems when billing for a procedure with status indicator C.

Scenario A: A procedure assigned status indicator C under the OPSS is performed to resuscitate or stabilize a beneficiary who appears with or suddenly develops a life-threatening condition. The patient dies during surgery or postoperatively before being admitted.

Scenario B: An elective or emergent surgical procedure payable under the OPSS is being performed. Because of sudden, unexpected intra-operative complications, the physician must alter the surgical procedure and perform a procedure with OPSS status

indicator C. The patient dies during the operation before he or she is admitted as an inpatient.

Scenario C: A procedure with status indicator C is performed to resuscitate or stabilize a beneficiary who appears with or suddenly develops a life-threatening condition. After the procedure, the patient is transferred to another facility for postoperative care.

3. Clarification of Payment Policy

We propose the following policy for fiscal intermediaries and providers to use in determining the appropriate Medicare payment in cases such as those described in the section above.

A procedure assigned status indicator C under the OPPS is never payable under the OPPS. Therefore, for a hospital to receive payment when a procedure with OPPS status indicator C is performed and: 1) the patient dies during or after the procedure, before being admitted, or 2) the patient survives the procedure and is transferred following the procedure, the patient's medical record must contain all of the following information:

- Either orders to admit written by the physician responsible for the patient's care at the hospital to which the patient was to be admitted, the hospital following the procedure for the purpose of receiving inpatient hospital

services and occupying an inpatient bed, or written orders to admit and transfer the patient to another hospital following the procedure.

- Documentation that the reported HCPCS code for the surgical procedure with OPPS payment status indicator C (such as CPT code 61345) was actually performed.
- Documentation that the reported surgical procedure with status indicator C was medically necessary.
- If the patient is admitted and subsequently transferred to another facility, documentation that the transfer was medically necessary, such as the patient requiring postoperative treatment unavailable at the transferring facility.

Because these services would be paid according to the appropriate DRG or per diem (see below), all services that were furnished before admission that would otherwise be payable under the OPPS would be paid in accordance with the provisions of section 3610.3 of the Medicare Intermediary Manual ("3-day rule") and section 415.6 of the Medicare Hospital Manual.

In the case of a patient who dies during performance of a procedure with OPPS status indicator C before being admitted, the hospital would submit a claim for all

services provided, including a line item for the status indicator C procedure. The claim would be rejected for payment under the OPPS and returned to the hospital. The hospital would resubmit the claim for payment as an inpatient stay under the appropriate DRG.

In the case of a patient who is admitted and transferred, the transferring hospital would be paid a per diem DRG rate if all the above conditions are met. (We propose to revise section 3610.5 of the Medicare Intermediary Manual accordingly.)

Note that a physician's order to admit a patient to an observation bed following a procedure designated with OPPS status indicator C would not constitute an inpatient admission and, therefore, would not qualify the procedure with status indicator C for payment. In this instance, the only allowable Medicare payment would be for a code payable under APC 0610, 0611, or 0612 if those services were provided. Payment would not be allowed for either the procedure with status indicator C or for any ancillary services furnished on the same date.

4. Orders to Admit

Some hospitals have raised questions about the timing of a physician's order to admit a patient. The requirements for the authenticating physician orders and

the standards for medical record keeping fall outside the scope of this proposed rule and OPPS payment policy. The payment guidelines proposed above are to assist hospitals and contractors in determining how to bill and pay for services appropriately under Medicare. The patient's admission status, as documented by the medical records, determines what Medicare payment is appropriate. Medical record keeping and documentation requirements are addressed in the Medicare hospital conditions of participation at § 482.24, and are governed by applicable State law and State licensing rules and hospital accreditation standards.

D. Status Indicators

The status indicators we assign to HCPCS codes and APCs under the OPPS have an important role in payment for services under the OPPS because they indicate if a service represented by a HCPCS code is payable under the OPPS or another payment system and also if particular OPPS policies apply to the code. We are providing our proposed status indicator assignments for APCs in Addendum A, HCPCS codes in Addendum B, and definitions of the status indicators in Addendum D.

The OPPS is based on HCPCS codes for medical and other health services. These codes are used for a wide variety of payment systems under Medicare, including, but not

limited to, the Medicare fee schedule for physician services, the Medicare fee schedule for durable medical equipment and prosthetic devices, and the Medicare clinical laboratory fee schedule. For purposes of making payment under the OPPS, we need a way to signal the claims processing system which HCPCS codes are paid under the OPPS and those codes to which particular OPPS payment policies apply. We accomplish this identification in the OPPS through the establishment of a system of status indicators with specific meanings. Addendum D defines the meaning of each status indicator for purposes of the OPPS.

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

Specifically, in 2003, we propose to use the status indicators in the following manner:

- We use "A" to indicate services that are paid under some payment method other than OPPS, such as the Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) fee schedule or the physician fee schedule. Some but not all of these other payment systems are identified in Addendum D.

- We use "C" to indicate inpatient services that are not payable under the OPPS.
- We use "D" to indicate a code that was deleted effective with the beginning of the calendar year.
- We use "E" to indicate services for which payment is not allowed under the OPPS or that are not covered by Medicare.
- We use "F" to indicate acquisition of corneal tissue, which is paid at reasonable cost.
- We use "G" to indicate drugs and biologicals that are paid under OPPS transitional pass-through rules.
- We use "H" to indicate devices that are paid under OPPS transitional pass-through rules.
- We use "K" to indicate drugs and biologicals (including blood and blood products) and certain brachytherapy seeds that are paid in separate APCs under the OPPS, but that are not paid under OPPS transitional pass-through rules.
- We use "N" to indicate services that are paid under the OPPS for which payment is packaged into another service or APC group.
- We use "P" to indicate services that are paid under the OPPS but only in partial hospitalization programs.

- We use "S" to indicate significant procedures that are paid under OPPS but to which the multiple procedure reduction does not apply.
- We use "T" to indicate significant services that are paid under the OPPS and to which the multiple procedure payment discount under OPPS applies.
- We use "V" to indicate medical visits (including clinic or emergency department visits) that are paid under the OPPS.
- We use "X" to indicate ancillary services that are paid under the OPPS.

The software that controls Medicare payment looks to the status indicators attached to the HCPCS codes and APCs for direction in the processing of the claim. Therefore, the assignment of the status indicators has significance for the payment of services. We sometimes change these indicators in the course of a year through Program Memoranda. Moreover, indicators are established for new codes that we establish in the middle of the year, either as a result of a national coverage decision or otherwise. A status indicator, as well as an APC, must be assigned so that payment can be made for the service identified by the new code.

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

E. Other Policy Issues Relating To Pass-Through Device Categories

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

In the November 30, 2001 final rule, we explain the methodology we used to estimate the portion of each APC rate that could reasonably be attributed to the cost of associated devices that are eligible for pass-through payments (66 FR 59904). Effective with implementation of the 2002 OPPS update on April 1, 2002, we deduct from the pass-through payments for those devices an amount that offsets the portion of the otherwise applicable APC payment amount that we determined is associated with the device, as required by section 1833(t)(6)(D)(ii) of the Act. In the March 1, 2002 final rule, we published the applicable offset amounts for 2002, which we had recalculated to reflect certain device cost assignments that were corrected in the same final rule (67 FR 9557).

For the 2003 OPPS update, we propose to estimate the portion of each APC rate that could reasonably be

attributed to the cost of an associated pass-through device that is eligible for pass-through payment using claims data for services furnished between July 1, 2001 through December 31, 2001. We propose to use only the last 6 months of 2001 claims data because bills for pass-through devices submitted during this time period would use only device category codes, allowing a more consistent analysis than would result were we to include pre-July 1 claims that might still show item-specific codes for pass-through devices. Using these claims, we would calculate a median cost for every APC without packaging the costs of associated C-codes for device categories that were billed with the APC. We would then calculate a median cost for every APC with the costs of associated C-codes for device categories that were billed with the APC packaged into the median. Comparing the median APC cost minus device packaging by the median APC cost including device packaging would allow us to determine the percentage of the median APC cost that is attributable to associated pass-through devices. By applying these percentages to the median APC cost, we would determine the applicable offset amount. Table 9 shows the offsets that we propose be applied in 2003 to each APC that contains device costs. APCs were included for offsets if their device costs comprised at

least 1 percent of the APC's costs. (However, if any APC's calculated offset had been less than 1 dollar, that APC and offset would not have been included.)

Table 9.—Proposed Offsets to be Applied For Each APC That Contains Device Costs

APC	Description	APC Percent attributed to devices	Device related cost to be subtracted from pass-through payment
0032	Insertion of Central Venous/Arterial Catheter	6.12%	\$22.73
0046	Open/Percutaneous Treatment Fracture or Dislocation	1.06%	\$16.00
0048	Arthroplasty with Prosthesis	5.78%	\$111.02
0051	Level III Musculoskeletal Procedures Except Hand and Foot	1.24%	\$21.95
0052	Level IV Musculoskeletal Procedures Except Hand and Foot	3.05%	\$67.21
0080	Diagnostic Cardiac Catheterization	4.36%	\$80.82
0081	Non-Coronary Angioplasty or Atherectomy	7.29%	\$86.03
0082	Coronary Atherectomy	47.58%	\$1,866.34
0083	Coronary Angioplasty and Percutaneous Valvuloplasty	20.08%	\$499.51
0085	Level II Electrophysiologic Evaluation	10.22%	\$168.87
0086	Ablate Heart Dysrhythm Focus	20.36%	\$462.74
0087	Cardiac Electrophysiologic Recording/Mapping	15.19%	\$45.90
0088	Thrombectomy	4.08%	\$72.06
0089	Insertion/Replacement of Permanent Pacemaker and Electrodes	68.56%	\$3,883.80
0090	Insertion/Replacement of Pacemaker Pulse Generator	64.17%	\$2,574.81
0091	Level II Vascular Ligation	1.75%	\$24.60
0093	Vascular Repair/Fistula Construction	1.63%	\$22.29
0104	Transcatheter Placement of Intracoronary Stents	40.26%	\$1,522.67
0105	Revision/Removal of Pacemakers, AICD, or Vascular	5.79%	\$57.64
0106	Insertion/Replacement/Repair of Pacemaker and/or Electrodes	18.05%	\$274.40
0107	Insertion of Cardioverter-Defibrillator	83.18%	\$7,852.32
0108	Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads	82.11%	\$9,936.93
0109	Removal of Implanted Devices	1.70%	\$6.79
0115	Cannula/Access Device Procedures	7.22%	\$88.17
0119	Implantation of Devices	13.61%	\$183.19
0122	Level II Tube changes and Repositioning	2.21%	\$4.47
0124	Revision of Implanted Infusion Pump	9.82%	\$119.87
0142	Small Intestine Endoscopy	1.03%	\$4.40
0151	Endoscopic Retrograde Cholangio-Pancreatography (ERCP)	2.71%	\$25.69
0152	Percutaneous Abdominal and Biliary Procedures	9.96%	\$32.01
0153	Peritoneal and Abdominal Procedures	1.69%	\$22.84
0154	Hernia/Hydrocele Procedures	2.66%	\$37.33
0167	Level III Urethral Procedures	11.54%	\$162.95
0168	Level II Urethral Procedures	5.20%	\$65.18
0179	Urinary Incontinence Procedures	34.30%	\$1,449.96
0182	Insertion of Penile Prosthesis	42.39%	\$1,847.50
0202	Level VIII Female Reproductive Proc	10.67%	\$216.92
0222	Implantation of Neurological Device	65.75%	\$4,806.58
0223	Implantation of Pain Management Device	11.54%	\$121.84
0225	Implantation of Neurostimulator Electrodes	33.33%	\$770.87
0226	Implantation of Drug Infusion Reservoir	70.33%	\$1,616.75
0227	Implantation of Drug Infusion Device	75.38%	\$5,019.34
0229	Transcatheter Placement of Intravascular Shunts	46.89%	\$1,194.96
0245	Level I Cataract Procedures without IOL Insert	3.24%	\$24.25

APC	Description	APC Percent attributed to devices	Device related cost to be subtracted from pass-through payment
0246	Cataract Procedures with IOL Insert	1.20%	\$14.72
0259	Level III ENT Procedures	75.29%	\$11,396.81
0279	Level II Angiography and Venography except Extremity	1.56%	\$6.82
0280	Level III Angiography and Venography except Extremity	5.02%	\$40.49
0281	Venography of Extremity	1.39%	\$3.78
0297	Level II Therapeutic Radiologic Procedures	1.91%	\$7.75
0656	Transcatheter placement of drug eluting stents	54.15%	\$2668.28
0670	Intravenous and Intracardiac Ultrasound	51.03%	\$392.26
0680	Insertion of Patient Activated Event Recorders	68.48%	\$1,850.24
0681	Knee Arthroplasty	64.57%	\$5,310.69
0684	Prostate Brachytherapy	67.49%	\$3631.89
0686	Level III Skin Repair	4.00%	\$23.51
0687	Revision/Removal of Neurostimulator Electrodes	1.50%	\$15.21
0688	Revision/Removal of Neurostimulator Pulse Generator Receiver	22.15%	\$352.28
0693	Level II Breast Reconstruction	1.00%	\$20.44
0981	New Technology - Level XII (\$2000 - \$2500)	13.32%	\$299.70

2. Devices Paid With Multiple Procedures

As explained above, under section 1833(t)(6)(D)(ii) of the Act, the amount of additional payment for a device eligible for pass-through payment is the amount by which the hospital's cost exceeds the portion of the otherwise applicable APC payment amount that the Secretary determines is associated with the device. Thus, for devices eligible for pass-through payment, we reduce the pass-through payment amount by the cost attributable to the device that is already packaged into the APC payment for an associated procedure. For 2002, we developed offset amounts, for 59 APCs (March 1, 2002 final rule, 67 FR 9556 through 9557, Table 1).

In our November 30, 2001 final rule (66 FR 59856), we articulated a policy regarding the calculation of the offsets for device costs already reflected in APCs in cases where the payment for the associated APC is reduced due to the multiple procedure discount. The policy was in response to several commenting parties that recommended that we apply the multiple procedure discount only to the non-device-related portion of the APC payment amount (66 FR 59906).

We agreed with the commenters that the full pass-through offset should not be applied when the APC payment is subject to the multiple procedure discount of 50 percent.

The purpose of the offset is to ensure that the OPSS is not making double payments for any portion of the cost associated with the use of the pass-through item. We stated in the November 30, 2001 rule that the offset should reflect that portion of the cost for the pass-through device actually reflected in the payment that is received for the associated APC. We consequently ruled that the most straightforward methodology for applying this principle is to reduce the amount of the offset amount by 50 percent whenever the multiple procedure discount applies to the associated APC. This discounting of the offset is

applied in 2002 to bills subject to multiple procedure discounting that also include devices eligible for pass-through payment.

The significant number of device categories that are expiring in 2003 combined with our proposal to package 100 percent of device costs into their associated APCs has prompted us to revisit the current policy of reducing offsets for pass-through devices in instances when multiple procedure discounts are applied to procedures associated with pass-through device categories. In order to determine the impact of multiple procedure discounting on APCs with full packaging of device costs, we reviewed the median costs of all APCs after incorporation of device costs and arrayed them in order of descending median cost. We also determined the contribution (in absolute dollars and as a percentage) of device costs to the median costs of each APC. We did this by examining claims submitted during the last 6 months of 2001 during which only device category codes were used to bill for pass-through devices because those were the only claims where we could specifically identify the contribution of device costs to the cost of each APC.

We then determined which APCs containing devices would be billed together. For example, the APC for insertion of

a pacemaker would not be billed with the APC for insertion of neurostimulator electrodes, whereas the APC for coronary stent placement might be billed with the APC for coronary angioplasty. We next determined, based on median cost data, which device containing APCs would be subject to the 50 percent multiple procedure reduction. After identifying these APCs, we applied a 50 percent reduction to arrive at a discounted payment amount. We then reviewed the contribution of device costs to the discounted APC both as a percentage and in absolute dollars to determine if applying the 50 percent reduction would result in underpayment for the service. We determined that the reduced payment was adequate to pay both for the devices incorporated into the APC and for the procedure cost in the context of performing multiple procedures. We obtained the same results even when we overstated device costs in our model by 5 or 10 percent to offset concerns expressed by some manufacturers and physicians that hospital charges for transitional pass-through devices may be understated.

To illustrate this analysis, assume APCs 0104 and 0083 are billed together. The median cost of APC 0104 is \$3,960 with 40 percent of the cost attributable to devices. The median cost of APC 0083 is \$2,605 with 20 percent of its cost attributable to devices. Under our existing multiple

procedure discount payment rules, APC 0104 would be paid at 100 percent, and APC 0083 would be paid at 50 percent. This means that payment for APC 0083 would be \$1,302 of which \$520 (20 percent of \$2,605) is attributable to devices. We believe this total payment accounts for the costs of the devices and the costs of the procedure when it is performed in conjunction with APC 0104.

We note that almost all APCs with high device costs (such as insertion of pacemakers, insertion of cardioverter-defibrillators, insertion of infusion pumps and neurostimulator electrodes) would never be subject to a multiple procedure discount. They have the highest relative weights in the OPPS, and we would not expect these procedures to be performed during the same operative session with a higher paying procedure with status indicator "T." Therefore, we propose to continue our current policy of multiple procedure discounting. That is, when two or more APCs with status indicator "T" are billed together we propose to pay 100 percent for the highest cost APC and 50 percent for all other APCs with status indicator "T." We propose not to adjust these payments to account for device costs in the APCs.

F. Outpatient Billing For Dialysis

Currently, hospitals are unable to bill for dialysis treatments furnished to End-Stage Renal Disease (ESRD) patients on an outpatient basis, unless the hospital also has a certified hospital-based ESRD facility. As a result of this policy, there has been an increase in denials by the PROs for inappropriate hospital admissions.

When ESRD patients come to the hospital for a medical emergency or for problems with their access sites, they typically miss their regularly scheduled dialysis appointments. If the ESRD patient's usual facility is unable to reschedule the dialysis treatment, the beneficiary has to wait until the next scheduled dialysis appointment. CMS is concerned that by maintaining this policy, beneficiaries may be receiving interrupted care because there will be unnecessary lapses in treatment. The ESRD patient should not be prevented from receiving her or his normal dialysis because he or she experienced another unrelated medical situation. Therefore, we propose to allow payment for dialysis treatments for ESRD patients in the outpatient department of a hospital in specific situations. Payment would be limited to unscheduled dialysis for ESRD patients in exceptional circumstances.

Outpatient dialysis for acute patients would not be included in this payment mechanism.

We propose to limit this payment to medical situations in which the ESRD patient cannot obtain her or his regularly scheduled dialysis treatment at a certified ESRD facility. Situations that we propose to allow are limited to: (1) dialysis performed following or in connection with a vascular access procedure; (2) dialysis performed following treatment for an unrelated medical emergency. For example, if a patient goes to the emergency room for chest pains and misses a regularly scheduled dialysis treatment that cannot be rescheduled, we would allow the hospital to provide and bill Medicare for the dialysis treatment; and 3) emergency dialysis - Currently, the only mechanism available for payment in this situation is through an inpatient admission. We will maintain our policy that routine treatments in non-ESRD certified hospitals would not be payable under OPSS.

We believe it is important to make this change in policy for two reasons: (1) to ensure that hospital outpatient departments are paid for providing this much needed service; and (2) to prevent dialysis patients from receiving interrupted care. Non-ESRD certified hospital outpatient facilities would bill Medicare using a new G

code, G0GGG, "Unscheduled or emergency treatment for dialysis for ESRD patient in the outpatient department of a hospital that does not have a certified ESRD facility." We propose that this new code will have status indicator "S" and be assigned to APC 0170. Payment would be roughly equivalent to the reimbursement rate for acute dialysis. We propose to implement this change effective January 1, 2003. Effective January 1, 2003, this would be the only way for non-ESRD certified hospital outpatient facilities to bill Medicare and be paid for providing outpatient dialysis to ESRD beneficiaries.

CMS will be monitoring the use of this new code to ensure that (1) certified dialysis facilities are not incorrectly using this code; and (2) the same dialysis patient is not repeatedly using this code, which would indicate routine dialysis treatment.

When ESRD patients receive outpatient dialysis in non-ESRD certified hospital outpatient facilities, the patient's home facility would be responsible for obtaining and reviewing the patient's medical records to ensure that appropriate care was provided in the hospital and that modifications are made, if necessary, to the patient's plan of care upon her or his return to the facility. This ensures continuity of care for the patient.

IX. Summary of and Responses to MedPAC Recommendations

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

Recommendation: For calendar year 2003, the Secretary should increase the payment rates for services covered by the OPPS by the rate of increase in the hospital market basket.

Response: Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor annually. Under section 1833(t)(3)(C)(iv) of the Act, the update is equal to the hospital market basket percentage increase applicable under the hospital inpatient PPS, minus one percentage point for the years 2000 and 2002. The Secretary has the authority under section 1833(t)(3)(C)(iv) of the Act to substitute a market basket that is specific to hospital outpatient services. In the September 8, 1998 proposed rule on the OPPS, we indicated that we were considering the option of developing an outpatient-specific market basket and invited comments on possible sources of data suitable for constructing one (63 FR 47579). We received no comments in response to this invitation, and we

therefore announced in the April 7, 2000 final rule that we would update the conversion factor by the hospital inpatient market basket increase, minus one percentage point, for the years 2000, 2001, and 2002 (65 FR 18502).

(As required by section 401(c) of the BIPA, we made payment adjustments effective April 1, 2001 under a special payment rule that had the effect of providing a full market basket update in 2001.) For 2003, we propose to increase payment rates by the rate of increase in the hospital market basket.

Recommendation: The Congress should—

- Replace hospital-specific payments for pass-through devices with national rates.
- Give the Secretary authority to consider alternatives to average wholesale price (AWP) when determining payments for pass-through drugs and biologicals.

Response: Regarding the pricing of transitional pass-through devices, we share the Commission's concern that the current methodology provides incentives for hospitals to inflate charges for transitional pass-through devices to increase payments. However, we believe that alternative approaches are not necessarily superior. Further, the salience of this problem should be much less in the future.

At present, the payment for a transitional pass-through device is set, on a claim-by-claim basis, relative to the hospital's charge for that device. The charge is reduced to a measure of cost by application of a hospital-specific cost-to-charge ratio, and a subtraction is made to reflect the portion of device costs already recognized in the payment for the associated procedure APC. This procedure means that a higher charge by a hospital will result in a higher payment from Medicare. The Commission notes that that this method embodies an incentive for hospitals, perhaps prompted by manufacturers, to increase charges as a means of increasing payments. The Commission is concerned that this situation may lead to excessive payments and may bias the charges used to revise, from year to year, relative weights in the OPPS.

In fact, the extent to which hospitals raising their charges on devices is problematic depends on the outcomes. In general, we anticipate that hospital charge structures, on average, reflect their costs; this assumption helps support the use of charge data to revise relative weights in hospital prospective payment systems. Accordingly, whether payments to hospitals for transitional pass-through devices might be considered excessive depends on whether hospitals inflate charges beyond the levels appropriate to

recover their costs. Whether their behavior leads to biases in charge data depends on whether they set charges on transitional pass-through devices significantly differently than on other services.

Moving to a fee schedule for transitional pass-through devices would remove the particular incentive problem that the Commission noted, which we agree would be desirable. However, the establishment of appropriate national rates would then become the focus. In the absence of field data on actual costs, we will be inevitably reliant on information that manufacturers provide. At present, manufacturers are asked for information about prices on applications for pass-through status. Anecdotal information suggests this information is not fully reliable as a measure of what hospitals actually pay.

The Commission's report discusses the possibility of CMS setting the rate for a device based on analysis of the manufacturer's costs, including an appropriate rate of return on equity. This approach would confront a number of accounting, legal, and operational difficulties.

- First, it would take some time to complete the analysis for a new product, which could significantly delay establishment of a rate. The rate that would be used in

the meantime, or whether billing would be permitted at all, would be open to question.

- Second, it appears that large firms with multiple product lines supply most devices, which would make determining the costs of a particular device difficult. This problem would be compounded when multiple enterprises are involved in bringing a product to market, which is not uncommon in the device industry, where invention and initial development may occur in one firm and final development, manufacturing, and marketing in another.

- Third, the government generally does not have access to manufacturers' cost information. While legal authority could be enhanced, manufacturers would face incentives that raise questions about the reliability of information provided, and the need for government accounting and auditing resources would be high.

- Fourth, as the Commission's report notes, an appropriate rate of return on equity would have to be established.

- Fifth, devices are now paid, under BIPA, on the basis of categories. As a result, if a manufacturer brings to market a product that fits the description of a category, hospitals can bill for that manufacturer's product without any change in coding or notification of

CMS. Consequently, we do not know what specific devices are actually being billed in these categories, or who manufactures them. Whatever rate might be established on the basis of an initial application for a category would presumably be based on the applicant's costs. Later entrants might have significantly different cost structures, but this information would not come into account unless a more elaborate process was implemented to include it.

Finally, whether a rate set in this fashion would pay less or more than the current method is unclear. The current method is based on actual experience in the field, and it will reflect, though perhaps somewhat tenuously, whatever competitive market pressures exist. Any method that we use aimed at ensuring a more reliable price could yield a price that is too high, since it will not reflect market activity. Whether a rate set by ex ante analysis of this sort would produce superior results does not appear obvious.

The Commission's report also mentions the possibility of using competitive bidding to set rates for transitional pass-through devices. While competitive bidding appears attractive as a means of setting a market-related price, it has not proven an easy process for

Medicare to implement. Competitive bidding seems best suited for established products with multiple suppliers. However, transitional pass-through devices are by definition new to the market and will frequently have only one manufacturer, at least at the start of the 2 to 3 year transitional pass-through period. Even in those instances in which this technique would be possible, it involves a fair amount of administrative resources and time, and using it to establish a rate that will be used at the most for 3 years does not appear to be an effective use of resources.

Both of the suggestions discussed above reflect procedures that involve relatively high overhead on the part of CMS and of other actors. It is not obvious whether either would produce results that are superior to those derived from the present method. While they would change incentives on hospitals, incentives of manufacturers would still be a source of concern. We agree with the Commission that further investigation would be necessary to determine a feasible alternative to cost-based pass-through payments.

In considering the advantages of various approaches, it is important to keep the size of the problem in mind, especially when contemplating procedures for setting rates that would involve substantial administrative resources. As of July 1, 2002, the OPBS pays for 100 categories of

devices. As is explained in section III.C of this preamble, we are proposing that 95 categories will lose pass-through status and be retired as of January 1, 2003.³ Since the initial categories were established in April 2001, we have added only three categories. While several applications are pending, given the extensiveness of the existing categories, it appears likely that the number of new categories to be established in future years will be small.⁴ The likely volume of claims represented by these new categories is of course speculative, but it also does not seem likely to be large relative to the size of the OPPS system. As discussed below, we developed criteria for the establishment of new categories that were specifically intended to limit future pass-through payments to devices that provide a substantial clinical improvement.

Considering that the identified alternatives do not appear to be manifestly superior to the current system but do involve significantly more administrative resources, and given the anticipated small volume of transitional pass-through devices in the future, we think on balance it would

³ In accord with the BBRA amendment that established the pass-through payment methodology, items are only eligible for pass-through payments for 2 to 3 years. After expiration of pass-through status, payments for devices described by these categories will be packaged into APC payments for the procedures with which they are used.

⁴ If a new device arrives on the market that would have fit in a category formerly in use but subsequently retired, it will not be eligible for pass-through payment.

be best to let more experience develop with the current system before making significant changes to the current method.

However, we agree that it would be desirable to give the Secretary authority to use alternatives to AWP when determining payments for pass-through drugs and biologicals. At present, total payment for these items is governed by the general rule (section 1842(o) of the Act) for Medicare pricing of drugs, which requires they be paid at 95 percent of AWP. This rule also covers most drugs delivered "incident to" physicians' services in physicians' offices and elsewhere. The Congress is at present considering various changes to the AWP as the basis for Medicare payment for drugs, and if a change is adopted to this standard, it may be an appropriate standard for transitional pass-through drugs and biologicals as well.

Recommendation: The Secretary should do the following:

- Ensure additional payments are made only for new or substantially improved technologies that are expensive in relation to the applicable ambulatory payment classification rate.
- Avoid basing national rates only on reported costs.

- Ensure that the same broad principles guide payments for new technologies in the inpatient and outpatient payment systems.

Response: We agree that additional payments should be limited to items that have the greatest merit and that have high costs not well captured in the existing payment structure. The Commission notes that limiting the number of transitional pass-through items limits the burdens on hospitals and us; reduces the likelihood of exceeding the statutory cap on aggregate pass-through payment, necessitating a uniform reduction in transitional pass-through payments; and limits the redistribution of funds across hospitals that are low versus high users of transitional pass-through items. We agree with these points. On November 2, 2001, we published an interim final rule with comment period in the **Federal Register** (66 FR 55850 to 55857) that set forth criteria we will use to evaluate whether to establish new categories of devices in the future. These criteria include tests of whether a device is new, whether it represents a substantial medical improvement for Medicare beneficiaries, and whether its costs are high relative to the payments that would otherwise be made.

Section 1833(t)(6)(D) of the Act prescribes the method for setting payment for transitional pass-through drugs and devices. The issue of possible alternatives is discussed above.

We agree that the same principles should govern payments for new technologies in the inpatient and outpatient prospective payment systems. Criteria governing extra new technology payments in the IPPS were established in a final rule published in the **Federal Register** (66 FR 46902 to 46925) on September 7, 2001. The criteria have the same general form as those for the OPPS. They differ in some particulars, largely traceable to the difference of the two payment systems. In particular, the IPPS system pays on the basis of an episode of care. As a result, the bundle of payment is generally larger and hospitals are better able to absorb minor cost differences. Considering the impact of new technology on all costs of the episode is also pertinent. Consequently, the criteria for special payment for inpatient new technologies require examination of the net effect on costs of the entire episode (not just the added costs of a new technology), and the relative cost standard we established is somewhat more stringent than for the OPPS. We believe it is premature to judge whether it will make sense to make these criteria

even closer in the future, as the Commission's discussion suggests.

X. Summary of Proposed Changes for 2003

A. Changes Required By Statute

We are proposing the following changes to implement statutory requirements:

- Add APCs, delete APCs, and modify the composition of some existing APCs.
- Recalibrate the relative payment weights of the APCs.
- Update the conversion factor and the wage index.
- Revise the APC payment amounts to reflect the APC reclassifications, the recalibration of payment weights, and the other required updates and adjustments.
- Cease transitional pass-through payments for drugs and biologicals (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 and Payment Suspension Provisions

We are proposing 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 HCPCS codes.
- Changes to our policies governing dialysis for ESRD patients and regarding partial hospitalization.

In addition, we are making changes to payment suspension policies.

C. Changes to the Regulations Text

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

- Amend §410.43(b) to add clinical social worker services (for the diagnosis and treatment of mental illnesses) that meet the requirements of section 1861(hh)(2) of the Act to the specified professional services that are separately covered and not paid as partial hospitalization services.

- 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.

XI. Summary of Proposed Payment Suspension Provisions

In this rule, we propose 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.

XII. Collection of Information Requirements

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

Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

This rule does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

XIII. Response to Public Comments

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

section of this preamble and respond to those comments in the preamble to that rule.

XIV. Regulatory Impact Analysis

The regulatory impact analysis for this proposed rule consists of an impact analysis for the OPPS provisions and a regulatory impact statement for the provision for payment suspension for unfiled cost reports.

A. OPPS

1. General

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 16, 1980 Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more annually).

We estimate the effects of the provisions that would be implemented by this proposed rule would result in

expenditures exceeding \$100 million in any 1 year. We estimate the total increase (from changes in the proposed rule as well as enrollment, utilization, and case mix changes) in expenditures under the OPPI for CY 2003 compared to CY 2002 to be approximately \$1.372 billion. Therefore, this proposed rule is an economically significant rule under Executive Order 12866, and a major rule under 5 U.S.C. 804(2).

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

For purposes of the RFA we have determined that approximately 37 percent of hospitals and 98 percent of mental health practitioners would be considered small entities according to the Small Business Administration (SBA) size standards. We do not have data available to calculate the percentages of entities in the pharmaceutical preparation manufacturing, biological products, or medical

instrument industries. For the pharmaceutical preparation manufacturing industry (NAICS 325412), the size standard is 750 or fewer employees and \$67.6 billion in annual sales (1997 business census). For biological products (except diagnostic) (NAICS 325414) \$5.7 billion and medical instruments (NAICS 339112), with \$18.5 billion in annual sales, the standard is 50 or fewer employees (see the standards web site at <http://www.sba.gov/regulations/siccodes/>). Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area (MSA) and has fewer than 100 beds (or New England County Metropolitan Area (NECMA)). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21) designated hospitals in certain New England counties as belonging to the adjacent

NECMA. Thus, for purposes of the OPPTS, we classify these hospitals as urban hospitals. We believe that the changes in this proposed rule would affect both a substantial number of rural hospitals as well as other classes of hospitals and that the effects on some may be significant. Therefore, we conclude that this proposed rule has a significant impact on a substantial number of small entities. However, the statute provides for small rural hospitals (of less than 100 beds) to be held harmless by the law and to continue to be paid at cost; therefore this proposed rule has no impact on them.

Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This proposed rule would not mandate any requirements for State, local, or tribal governments. This proposed rule imposes no unfunded mandates on the private sector.

Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that it will not have an impact on the rights, roles, and responsibilities of State, local or tribal governments. The impact analysis (see table 10) shows that payments to governmental hospitals (including State, local and tribal governmental hospitals) would increase by 5 percent under the proposed rule.

2. Changes in this Proposed Rule

We are proposing several changes to the OPPS that are required by the statute. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the conversion factor used to determine the APC payment rates. We are also required under section 1833(t)(9)(A) of the Act to revise, not less often than annually, the wage index and other adjustments. In addition, we must review the clinical integrity of payment groups and weights at least annually. Accordingly, in this proposed rule, we are updating the conversion factor and the wage index

adjustment for hospital outpatient services furnished beginning January 1, 2003 as we discuss in sections VI and IV, respectively, of this preamble. We are also proposing revisions to the relative APC payment weights based on claims data from January 1, 2001 through December 31, 2001. Finally, we are proposing to remove 95 devices and more than 200 drugs and biologicals from pass-through payment status.

Under this proposed rule, the change to the conversion factor as provided by statute would increase total OPPS payments by 3.5 percent in 2003. The changes to the wage index and to the APC weights (which incorporates the cessation of pass-through payments for many drugs and devices) do not increase OPPS payments because the OPPS is budget neutral. However, the wage index and APC weight changes do change the distribution of payments within the budget neutral system as shown in Table 10 and described in more detail in this section.

Alternatives Considered

Alternatives to the changes we propose and the reason that we did not choose to propose them are discussed throughout this proposed rule. Below we discuss options we considered when analyzing methodologies to appropriately recognize the costs of former pass-through items. For a

more detailed discussion, see section III.C.1 regarding the expiration of pass-through payment for devices and section III.C.2 regarding the expiration of pass-through payment for drugs and biologicals.

Payment for Categories of Devices

We considered establishing separate APCs for categories of devices and paying for them separately. We did not propose this option because we believe that to the extent possible, hospital payment for procedures and visits should include all of the costs required to provide the procedures and visits.

A second option we considered involved (1) packaging some categories of devices into the procedures with which they were billed in 2001 and (2) paying the rest through separate APCs (as discussed in section III.C.). We did not propose this option because we believe that devices are routinely used in the services for which they are needed and therefore are consistently paid at the cost of providing the service. Furthermore, criteria that would provide a basis for some devices to be packaged and for others to be paid separately would have to be developed and approved, thereby further complicating an already complex payment system.

Payment for Drugs and Biologicals

We considered continuing to make separate payment for all drugs and biologicals through separate APCs. We did not propose to pay separately for all drugs through separate APCs because we believe that, to the extent possible, hospital payment for services should include all of the costs of the services. We believe that drugs should be packaged with the services in which they are furnished except when we determine that there is a valid reason to do otherwise. However, we recognize that (unlike the stability that exists with device usage with the applicable procedures) the use of drugs may vary widely depending upon patient and disease characteristics. Therefore, packaging payment for all drugs may, in some cases, provide inadequate payment for the services furnished. Where a hospital has a disproportionate share of patients who need greater amounts of expensive drugs, underpayment for the drugs needed by these patients could result in cessation of needed services. For the first year that we are ceasing transitional pass-through payment for drugs, we decided to proceed cautiously by proposing to pay separately for drugs when the cost per encounter was more than \$150 or when special characteristics existed (for example, orphan drugs, blood products).

We also considered packaging the costs of all drugs into the cost of the associated procedures with which they were billed in 2001. We did not package all payment for drugs into the payment for the procedures because, while this packaging is ultimately our goal, we believe, for the reasons indicated above, that we need to proceed cautiously to ensure that we do not inadvertently threaten access to needed care.

Conclusion

It is clear that the changes in this proposed rule would affect both a substantial number of rural hospitals as well as other classes of hospitals, and the effects on some may be significant. Therefore, the discussion below, in combination with the rest of this proposed rule, constitutes a regulatory impact analysis.

The OPPS rates proposed for CY 2003 would have, overall, a positive effect for every category of hospital with the exception of children's hospitals, which are held harmless under the OPPS. The changes in the OPPS proposed for 2003 would result in an overall 3.5 percent increase in Medicare payments to hospitals, exclusive of outlier and transitional pass-through payments and transitional corridor payments. As described in the preamble, budget

neutrality adjustments are made to the conversion factor and the weights to assure that the revisions in the wage index, APC groups, and relative weights do not affect aggregate payments. The impact of the wage and recalibration changes does vary somewhat by hospital group. Estimates of these impacts are displayed on Table 10.

The overall projected increase in payments for urban hospitals is slightly lower (2.5 percent) than the average increase for all hospitals (3.5 percent) while the increase for rural hospitals is significantly greater (7.6 percent) than the average increase. Rural hospitals gain 2.3 percent from the wage index change, and also gain 1.6 percent from APC changes. A discussion of the distribution of outlier payments that we project under this proposed rule can be found under section D below. Table 11 presents the outlier distribution that we expect to see under this proposed rule.

3. Limitations of Our Analysis

The distributional impacts represent the projected effects of the proposed policy changes, as well as statutory changes effective for 2003, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per service while holding all other payment policies constant. We use the best data

available but do not attempt to predict behavioral responses to our policy changes. In addition, we do not make adjustments for future changes in variables such as service volume, service mix, or number of encounters.

4. Estimated Impacts of this Proposed Rule on Hospitals

The OPSS is a budget neutral payment system under which the increase to the total payments made under OPSS is limited by the increase to the conversion factor set under the methodology in the statute. The impact tables show the redistributive effects of the wage index and APC changes. In some cases, under this proposed rule, hospitals would receive more total payment than in 2002 while in other cases they would receive less total payment than they received in 2002. The impact of this proposed rule would depend on a number of factors, most significant of which are the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would change) and the impact of the wage index changes on the hospital.

Column 4 in Table 10 represents the full impact on each hospital group of all the changes for 2003. Columns 2 and 3 in the table reflect the independent effects of the proposed change in the wage index and the APC reclassification and recalibration changes, respectively.

We excluded critical access hospitals (CAHs) from the analysis of the impact of the proposed 2003 OPPS rates that is summarized in Table 10. For that reason, the total number of hospitals included in Table 10 (4,551) is lower than in previous years. CAHs are excluded from the OPPS.

In general, the wage index changes favor rural hospitals, particularly the largest in bed size and volume. The only rural hospitals that would experience a negative impact due to wage index changes are those in Puerto Rico, a decrease of 2.8 percent. Conversely, the urban hospitals are generally negatively affected by wage index changes, with the largest decreases occurring in those with 300-499 beds (-0.7 percent) and those in the Middle Atlantic (-1.3 percent), Pacific (-.09 percent) and Puerto Rico Regions ((-1.8 percent). However, this effect is somewhat lessened by the distribution of outlier payments as discussed in more detail below.

The APC reclassification and recalibration changes also favor rural hospitals and have a negative effect on urban hospitals in excess of 200 beds. Specifically, urban hospitals with 200-299 beds (-0.5 percent decrease), urban hospitals with 300-499 beds (-2.0 percent decrease) and urban hospitals in excess of 500 beds (a -1.9 percent decrease) all show a decrease attributed to APC

recalibration. We believe this occurs as a result of our folding 75 percent of estimated pass-through device costs into APC payments in the 2002 OPSS. Specifically, a comparison of the relative payment weights proposed for 2003, as listed in Addendum A, with the final 2002 relative payment weights in the March 1, 2002 final rule shows a decrease in the weights for certain APCs in 2002 that included a fold-in of 75 percent of estimated pass-through device costs. We relied on cost information supplied by device manufacturers in estimating the device costs to be folded in when calculating the median APC costs for the 2002 OPSS, whereas the proposed 2003 relative payment weights are based on actual hospital charges and utilization under the OPSS as reported by hospitals. We believe this downward tendency in the payment weights for APCs that include device costs, based on actual hospital experience, accounts in part for the lower positive effect of the proposed 2003 rates on urban hospitals and on teaching hospitals, which tend to perform a higher number of procedures involving costly new technology devices, in contrast with an increased positive effect in 2003 on rural and non-teaching hospitals, which tend to furnish a higher volume of clinic and preventive services than procedures associated with expensive new technology devices.

In both urban and rural areas, hospitals that provide a lower volume of outpatient services are projected to receive a larger increase in payments than higher volume hospitals. In rural areas, hospitals with volumes of fewer than 5000 services are projected to experience a significant increase in payments (8.1 percent). The less favorable impact for the high volume urban hospitals is attributable to both wage index and APC changes. For example, urban hospitals providing more than 42,999 services are projected to gain a combined 1.6 percent due to these changes.

Major teaching hospitals are projected to experience a smaller increase in payments (1.7 percent) than the aggregate for all hospitals (3.5 percent) due to negative impacts of the wage index (-0.5 percent) and recalibration (-1.2 percent). Hospitals with less intensive teaching programs are projected to experience an overall increase (2.0 percent) that is smaller than the average for all hospitals. There is little difference in impact among hospitals with that serve low-income patients.

TABLE 10.--IMPACT OF CHANGES FOR CY 2003 HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

[Percent change in total payment to hospitals (program and beneficiary); does not include the effects of outlier and transitional pass-through payments or of transitional corridor payments.]

Number of Hospitals ¹	New Wage Index ²	APC Changes ³	All CY 2003 Changes ⁴
(1)	(2)	(3)	(4)

ALL HOSPITALS	4,551	0.0	0.0	3.5
NON-TEFRA HOSPITALS	4,002	0.0	-0.1	3.4
URBAN HOSPS	2,429	-0.6	-0.5	2.5
LARGE URBAN	1,398	-0.7	-0.1	2.6
(GT 1 MILL.)				
OTHER URBAN	1,031	-0.4	-0.9	2.2 (LE 1
MILL.)				
RURAL HOSPS	1,573	2.3	1.6	7.6
BEDS (URBAN)				
0 - 99 BEDS	554	-0.3	3.1	6.4
100-199 BEDS	882	-0.6	1.4	4.3
200-299 BEDS	488	-0.6	-0.5	2.3
300-499 BEDS	364	-0.7	-2.0	0.7
500 + BEDS	141	-0.3	-1.9	1.3
BEDS (RURAL)				
0 - 49 BEDS	754	0.4	2.9	7.0
50- 99 BEDS	479	1.5	2.3	7.6
100- 149 BEDS	201	2.4	1.5	7.6
150- 199 BEDS	73	5.5	0.1	9.5
200 + BEDS	66	3.3	0.0	7.0
VOLUME (URBAN)				
LT 5,000	188	0.9	6.5	10.9
5,000 - 10,999	305	-0.8	5.1	7.9
11,000 - 20,999	472	-0.7	2.6	5.5
21,000 - 42,999	657	-0.8	0.3	3.0
GT 42,999	807	-0.5	-1.4	1.6
VOLUME (RURAL)				
LT 5,000	326	0.2	4.2	8.1
5,000 - 10,999	446	0.6	4.4	8.7
11,000 - 20,999	373	1.3	2.7	7.7
21,000 - 42,999	290	1.9	1.4	6.9
GT 42,999	138	4.3	-0.2	7.8
REGION (URBAN)				
NEW ENGLAND	127	-0.6	0.6	3.4
MIDDLE ATLANTIC	372	-1.3	0.2	2.3
SOUTH ATLANTIC	370	-0.2	-0.1	3.2
EAST NORTH CENT.	413	-0.7	-1.4	1.4
EAST SOUTH CENT.	153	-0.6	-1.0	1.9
WEST NORTH CENT.	172	-0.3	-1.6	1.6
WEST SOUTH CENT.	293	0.5	-0.7	3.3
MOUNTAIN	122	-0.4	-1.1	1.9
PACIFIC	368	-0.9	0.6	3.1
PUERTO RICO	39	-1.8	4.7	6.4
REGION (RURAL)				
NEW ENGLAND	40	1.6	1.3	6.5
MIDDLE ATLANTIC	63	2.2	1.3	7.2
SOUTH ATLANTIC	226	2.6	2.1	8.4
EAST NORTH CENT.	213	1.2	-0.2	4.6
EAST SOUTH CENT.	232	2.3	2.6	8.7
WEST NORTH CENT.	271	2.0	0.9	6.6
WEST SOUTH CENT.	278	1.8	3.2	8.8
MOUNTAIN	141	4.1	1.3	9.2
PACIFIC	104	5.6	2.7	12.1
PUERTO RICO	5	-2.8	10.4	11.1
TEACHING STATUS				

NON-TEACHING	2,935	0.4	1.1	5.0
MINOR	782	-0.4	-1.1	2.0
MAJOR	284	-0.5	-1.2	1.7
DSH PATIENT PERCENT				
0	11	4.9	10.1	19.4
GT 0 - 0.10	982	-0.2	-0.4	3.0
0.10 - 0.16	873	0.7	-0.8	3.4
0.16 - 0.23	767	-0.6	-0.3	2.6
0.23 - 0.35	756	-0.2	0.1	3.4
GE 0.35	613	-0.1	2.2	5.8
URBAN IME/DSH				
IME & DSH	982	-0.7	-1.2	1.6
IME/NO DSH	0	0.0	0.0	0.0
NO IME/DSH	1,441	-0.4	0.7	3.8
NO IME/NO DSH	6	5.4	9.8	19.7
RURAL HOSP. TYPES				
NO SPECIAL STATUS	610	0.7	2.7	7.1
RRC	167	4.2	0.2	8.2
SCH/EACH	507	1.5	2.7	7.8
MDH	199	0.8	2.1	6.6
SCH AND RRC	75	4.0	0.5	8.2
TYPE OF OWNERSHIP				
VOLUNTARY	2,440	-0.1	-0.4	3.1
PROPRIETARY	707	-0.6	0.9	3.8
GOVERNMENT	855	0.7	0.7	5.0
SPECIALTY HOSPITALS				
EYE AND EAR	13	-1.4	11.5	13.7
TRAUMA	153	-0.3	-1.5	1.6
CANCER	10	0.5	-3.9	0.2
TEFRA HOSPITALS (NOT INCLUDED ON OTHER LINES)				
REHAB	166	10.3	2.8	16.9
PSYCH	198	0.1	15.9	20.1
LTC	143	1.3	15.9	20.4
CHILDREN	42	-1.4	-2.8	-0.9

Note: For CY 2003, under the OPPI transitional corridor policy, the following categories of hospitals are held harmless compared to their 1996 payment margin for these services: cancer and children's hospitals and rural hospitals with 100 or fewer beds.

¹Some data necessary to classify hospitals by category were missing; thus, the total number of hospitals in each category may not equal the national total.

²This column shows the impact of updating the wage index used to calculate payment by applying the proposed FY 2003 hospital inpatient wage index after geographic reclassification by the Medicare Geographic Classification Review Board. The hospital inpatient proposed rule for FY 2003 was published in the Federal Register on May 9, 2002.

³This column shows the impact of changes resulting from the reclassification of HCPCS codes among APC groups and the recalibration of APC weights based on 2001 hospital claims data.

⁴This column shows changes in total payment from CY 2002 to CY 2003, excluding outlier and pass-through payments. It incorporates all of the changes reflected in columns 2 and 3. In addition, it shows the impact of the

proposed CY 2003 payment update. The sum of the columns may be different from the percentage changes shown here due to rounding.

As stated elsewhere in this preamble, we propose to allocate 2 percent of the estimated 2003 expenditures to outlier payments. In Table 11 below, we provide a distribution by percentage of the total projected outlier payments for the categories of hospitals that we show in the impact table (Table 10).

We project, based on the mix of services for the hospitals that will be paid under the OPPS in 2003, that most hospitals will receive outlier payments. It appears that, with the exception of some smaller bed hospitals, all Tax Equity & Fiscal Responsibility Act of 1982 (TEFRA) hospitals can be expected to receive outlier payments. This is because TEFRA hospitals provide an atypical mix of specialty services (which account for less than 1 percent of total OPPS payment before consideration of outliers). A greater percentage of non-TEFRA hospitals are not projected to receive outlier payments.

The anticipated outlier payments for urban hospitals can be expected to ameliorate the impact of the wage index and APC changes on payments to urban hospitals.

**TABLE 11.--DISTRIBUTION OF OUTLIER PAYMENTS FOR CY 2003 HOSPITAL
OUTPATIENT PROSPECTIVE PAYMENT SYSTEM**

Number of hosps	Percent of total hosps	Number of hosps with outliers	Percent of total outlier payments
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ALL HOSPITALS	4,551	100.00	4,306	100.00
NON-TEFRA HOSPITALS	4,002	88.00	3,987	99.40
URBAN HOSPS	2,429	53.40	2,420	83.20
LARGE URBAN (GT 1 MILL.)	1,398	30.80	1,396	55.20
OTHER URBAN (LE 1 MILL.)	1,031	22.60	1,024	28.00
RURAL HOSPS	1,573	34.60	1,567	16.00
BEDS (URBAN)				
0 - 99 BEDS	554	12.20	550	6.80
100-199 BEDS	882	19.40	877	18.20
200-299 BEDS	488	10.80	488	16.20
300-499 BEDS	364	8.00	364	21.00
500 + BEDS	141	3.00	141	21.00
BEDS (RURAL)				
0 - 49 BEDS	754	16.60	751	4.20
50- 99 BEDS	479	10.60	477	5.00
100- 149 BEDS	201	4.40	200	2.60
150- 199 BEDS	73	1.60	73	2.00
200 + BEDS	66	1.40	66	2.40
VOLUME (URBAN)				
LT 5,000	188	4.20	180	1.00
5,000 - 10,999	310	6.80	309	2.80
11,000 - 20,999	467	10.20	467	7.00
21,000 - 42,999	659	14.40	659	15.80
GT 42,999	805	17.60	805	56.60
VOLUME (RURAL)				
LT 5,000	326	7.20	321	1.00
5,000 - 10,999	447	9.80	446	2.60
11,000 - 20,999	372	8.20	372	3.80
21,000 - 42,999	290	6.40	290	4.20
GT 42,999	138	3.00	138	4.40
REGION (URBAN)				
NEW ENGLAND	127	2.80	126	6.20
MIDDLE ATLANTIC	372	8.20	371	22.80
SOUTH ATLANTIC	370	8.20	369	11.00
EAST NORTH CENT.	413	9.00	409	15.60
EAST SOUTH CENT.	153	3.40	152	3.40
WEST NORTH CENT.	172	3.80	172	4.40
WEST SOUTH CENT.	293	6.40	292	8.20
MOUNTAIN	122	2.60	122	3.00
PACIFIC	368	8.00	368	8.60
PUERTO RICO	39	0.80	39	0.20
REGION (RURAL)				
NEW ENGLAND	40	0.80	40	1.00
MIDDLE ATLANTIC	63	1.40	63	1.00
SOUTH ATLANTIC	226	5.00	223	3.00
EAST NORTH CENT.	213	4.60	212	3.00
EAST SOUTH CENT.	232	5.00	232	1.60
WEST NORTH CENT.	271	6.00	270	2.40
WEST SOUTH CENT.	278	6.20	278	1.60
MOUNTAIN	141	3.00	141	1.40
PACIFIC	104	2.20	103	1.20

PUERTO RICO	5	0.20	5	0.00
TEACHING STATUS				
NON-TEACHING	2,935	64.40	2,920	39.80
MINOR	782	17.20	782	27.20
MAJOR	284	6.20	284	32.20
DSH PATIENT PERCENT				
0	11	0.20	10	0.00
GT 0 - 0.10	982	21.60	978	24.80
0.10 - 0.16	873	19.20	873	19.40
0.16 - 0.23	767	16.80	765	17.60
0.23 - 0.35	756	16.60	753	20.00
GE 0.35	613	13.40	608	17.40
URBAN IME/DSH				
IME & DSH	982	21.60	982	57.20
IME/NO DSH	0	0.00	0	0.00
NO IME/DSH	1,441	31.60	1,433	26.00
NO IME/NO DSH	6	0.20	5	0.00
RURAL HOSP. TYPES				
NO SPECIAL STATUS	621	13.60	617	5.20
RRC	167	3.60	166	4.00
SCH/EACH	511	11.20	511	4.40
MDH	199	4.40	198	1.00
SCH AND RRC	75	1.60	75	1.40
TYPE OF OWNERSHIP				
VOLUNTARY	2,440	53.60	2,435	73.60
PROPRIETARY	707	15.60	702	10.40
GOVERNMENT	855	18.80	850	15.20
SPECIALTY HOSPITALS				
EYE AND EAR	13	0.20	13	0.20
TRAUMA	153	3.40	153	15.00
CANCER	10	0.20	10	3.80
TEFRA HOSPITALS (NOT INCLUDED ON OTHER LINES)				
REHAB	166	3.60	113	0.20
PSYCH	198	4.40	65	0.20
LTC	143	3.20	100	0.20
CHILDREN	42	1.00	41	0.20

5. Estimated Impacts of this Proposed Rule on Beneficiaries

For services for which the beneficiary pays a coinsurance of 20 percent of the payment rate, the beneficiary share of payment would increase for services for

which OPPS payments would rise and would decrease for services for which OPPS payments would fall. For example for a mid level office visit (APC 0601), the minimum unadjusted copayment in 2002 was \$9.67; under this proposed rule, the minimum unadjusted copayment would be \$10.82 because the OPPS payment for the service would increase under this proposed rule. For some services (those services for which a national unadjusted copayment amount is shown in Addendum B), however, the beneficiary copayment is frozen based on historic data and would not change, therefore not presenting any potential impact on beneficiaries.

However, in all cases, the statute limits beneficiary liability for copayment for a service to the inpatient hospital deductible for the applicable year. This amount was \$812 for 2002, but is not yet determined for 2003. In general, the impact of this proposed rule on beneficiaries would vary based on the service the beneficiary receives and whether the copayment for the service is one that is frozen under the OPPS.

B. Payment Suspension for Unfiled Cost Reports

Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section

1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132. (A description of each of these requirements is stated above in section XIV.A.1.)

We have determined that the proposed payment suspension provision does not have an economic impact on Medicare payments or other payments to providers. We are proposing to allow the Secretary flexibility in payment suspensions, but we are not altering the final payment determination in any way. With the implementation of the various prospective payment systems, the majority of the payment to providers is based on the PPS methodology and not on the cost report. Suspending all payments because the cost report is not timely filed negatively affects providers. Providing the Secretary with flexibility in payment suspension can lessen the financial impact on providers. For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals. Under the requirement for Unfunded Mandates, this proposed rule will not have an economic

effect on State, local, or tribal governments, in the aggregate, or on the private sector.

Anticipated Effects

1. Effects on providers that file cost reports. The majority of providers that file cost reports comply with the timeliness provisions and will be unaffected by this proposed regulation. In FY 2000, collectively 16 percent of hospitals, skilled nursing facilities, and home health agencies filed late cost reports. Of this 16 percent, 65 percent of those were only 1 day late. Currently, when a provider fails to file an acceptable cost report, the provider is placed on a complete payment suspension. Under this provision, for those providers who do not file timely, an immediate payment suspension less than the total suspension currently required might be imposed if the Secretary deemed it appropriate, which would allow the provider to more easily continue operations while completing and submitting the acceptable cost report.

2. Effects on other providers.

The payment suspension provision does not affect other providers.

3. Effects on the Medicare Program.

The provision would allow the Secretary to more effectively manage the Medicare program by imposing other

than complete payment suspension when it is appropriate to do so. The Medicare program benefits because immediate complete payment suspension can be disruptive to providers and may negatively affect the care of Medicare patients. There are no costs to the Medicare program to doing so, because when the cost report is submitted, the suspended payments are returned to the provider.

4. Effects on Beneficiaries

We have determined that this provision has a potentially positive impact on beneficiaries. Under this proposed provision the Secretary will have the discretion to impose less than 100 percent payment suspension when a provider fails to timely file an acceptable cost report. Doing so will lessen the financial burden on the provider and thereby allow it to provide adequate services to its patient population as it works to complete and file an acceptable cost report.

Alternatives Considered

We considered not revising existing §405.371(c) to provide that payment suspension could be "in whole or in part". However, we did not choose this option because we believe the Secretary should have the discretion to impose partial payment suspensions when circumstances warrant in order to more effectively manage the Medicare program.

Conclusion

In conclusion, we have determined that the proposed payment suspension provision does not have an economic impact on Medicare payments.

Federalism

Since this regulation does not impose any costs on State or local governments, it will not have an effect on State or local governments. State or local governments will have no roles or responsibilities associated with this provision.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects**42 CFR Part 405**

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 405-FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED
Subpart C-Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

1. The authority citation for subpart C continues to read as follows:

Authority: Secs. 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.

2. Section 405.371(c) is revised to read as follows:

§405.371 Suspension, offset and recoupment of Medicare payments to providers and suppliers of services.

* * * * *

(c) Suspension of payment in the case of unfiled cost reports. If a provider has failed to timely file an acceptable cost report, payment to the provider is immediately suspended in whole or in part until a cost report is filed and determined by the intermediary to be acceptable. In the case of an unfiled cost report, the provisions of §405.372 do not apply. (See §405.372(a)(2) concerning failure to furnish other information.)

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In 410.43 republish the introductory text of paragraph (b), and add a new paragraph (b) (6) to read as follows:

§410.43 Partial hospitalization services: Conditions and exclusions.

* * * * *

(b) The following services are separately covered and not paid as partial hospitalization services:

* * * * *

(6) Clinical social worker services that meet the requirements of section 1861(hh) (2) of the Act.

**PART 419--PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL
OUTPATIENT DEPARTMENT SERVICES**

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

§419.66 [Amended]

2. In §419.66, paragraph (c) (1) is amended by adding the phrase "or by any category previously in effect" after "categories" and before "and".

Catalog of Federal Domestic Assistance Program No. 93.773,
Medicare--Hospital Insurance; and Program No. 93.774,
Medicare--Supplementary Medical Insurance Program)

Dated: _____

Thomas A. Scully,

Administrator, Centers for

Medicare & Medicaid Services.

Approved: _____

Tommy G. Thompson,

Secretary.

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