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Centers for Medicare & Medicaid Services

42 CFR Part 419

**Medicare Program—Prospective Payment
System for Hospital Outpatient Services;
Final Rules**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 419

[CMS-1179-IFC]

RIN 0938-AK59

Medicare Program—Prospective Payment System for Hospital Outpatient Services: Criteria for Establishing Additional Pass-Through Categories for Medical Devices

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period sets forth the criteria the Secretary will use to establish new categories of medical devices eligible for transitional pass-through payments under Medicare's hospital outpatient prospective payment system.

DATES: *Effective date:* These regulations are effective December 3, 2001.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 2, 2002.

ADDRESSES: Mail an original and 3 copies of written comments to the following address only:

Centers for Medicare & Medicaid Services
Department of Health and Human Services, Attention: CMS-1179-IFC, P.O. Box 8018, Baltimore, MD 21244-8018
Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201, or
Room C5-16-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS-1179-IFC.

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beginning of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT:

Nancy Edwards, (410) 786-0378 or Barry Levi, (410) 786-4529.

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, in Room C5-10-04 of the Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD, on Monday through Friday of the week from 8:30 a.m. to 5 p.m. Please call (410) 786-7195 or (410) 786-4668 to view these comments.

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I. Background

Section 1833(t) of the Social Security Act (the Act), as added by section 4523 of the Balanced Budget Act of 1997 (BBA), Pub. L. 105-133, provided for implementation of a prospective payment system (PPS) for hospital outpatient services furnished to Medicare beneficiaries. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Pub. L. 106-113, amended section 1833(t) of the Act to make major changes that affected the new PPS for hospital outpatient services. On April 7, 2000, we published in the **Federal Register** (65 FR 18434), a final rule with comment

period to implement the new PPS for hospital outpatient services. The new system establishes payment rates for each service paid under this system using ambulatory payment classification (APC) groups. On June 30, 2000, we published a notice in the **Federal Register** (65 FR 40535) announcing a delay in the effective date of the hospital outpatient PPS (OPPS) from July 1, 2000 (as set forth in the April 7, 2000 final rule) until August 1, 2000. Therefore, OPPS became effective on August 1, 2000. The regulations implementing the payment system appear at 42 CFR part 419.

Among the provisions of the April 7, 2000 final rule with comment period are those implementing section 1833(t)(6) of the Act, which was added by section 201(b) of the BBRA. This section provided for temporary additional payments, referred to as "transitional pass-through payments," for certain drugs, biologicals, and devices. The provision required the Secretary to make additional payments to hospitals for at least 2, but no more than 3, years for specific items. The items designated by the BBRA are as follows:

- Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act.
- Current drugs, biologicals, and brachytherapy devices used for the treatment of cancer.
- Current radiopharmaceutical drugs and biologicals.
- New medical devices, drugs, and biologicals in instances in which the item was not being paid as a hospital outpatient service as of December 31, 1996, and when the cost of the item is "not insignificant" in relation to the OPPS payment amount. For those drugs, biologicals, and devices referred to as "current," the transitional payment begins on the first date the hospital OPPS is implemented, as required by section 1833(t)(6)(B)(i) of the Act (before enactment of the Medicare, Medicaid, and SCHIP Program Benefits Improvement and Protection Act (BIPA), Pub. L. 106-554, enacted December 21, 2000).

Section 1833(t)(6)(B) of the Act requires payment to be made on a "pass-through" basis for the designated items. Specifically, for devices, the payment is determined by taking the hospital's charge for the device on the individual claim submitted to Medicare, multiplying by the hospital's cost-to-charge ratio, and subtracting an amount identified by the Secretary as already included in the associated APC to reflect payment for similar devices.

In the April 7, 2000 final rule with comment period, we discussed the

criteria that we will use to determine which medical devices are eligible for transitional pass-through payments. These criteria were further discussed and several modifications were made in an interim final rule with comment period published in the **Federal Register** on August 3, 2000 (65 FR 47670). The modifications included changes in the test used to determine when the cost of the item is "not insignificant." Effective August 1, 2000, we used these criteria in determining which devices were eligible for transitional pass-through payments.

From the initial implementation of the new system on August 1, 2000 through March 31, 2001, we determined eligibility for all medical devices (as well as drugs and biologicals) for transitional pass-through payment on an item-specific basis, that is, distinguishing by individual trade names (and, in some instances, model numbers) of the eligible devices. Devices that we determined eligible were listed in one of a number of Program Memoranda we published on this subject. These lists were also posted on our Web site, www.hcfa.gov. Other devices, even if similar to those on the published lists, were not eligible in the absence of a specific eligibility decision published in a Program Memorandum. We established a quarterly process by which interested parties could submit applications to us for eligibility determinations for particular devices. Using this process, we determined that over 1,000 devices were eligible for transitional pass-through payments.

The most significant reason for adopting an item-specific approach rather than a category approach, which was also considered, was the requirement in section 1833(t)(6)(A)(iv)(I) of the Act that, for a device to be eligible for a transitional pass-through payment, "payment for the device * * * as an outpatient hospital service under this part was not being made as of December 31, 1996." We adopted an item-specific approach in order to distinguish which devices met this criterion. If we had adopted a categorical approach, any category that contained any device that Medicare had paid for before 1997 would not be eligible for transitional pass-through payments. No device included in that category, regardless of when Medicare started to pay for it, would be eligible. This approach would have severely limited the eligibility of devices for transitional pass-through payments, a result that we believed was contrary to the intent of the statute. Our reasons for adopting an item-specific approach to determining eligibility of transitional

pass-through payments are further discussed in the November 13, 2000 interim final rule with comment period (65 FR 67806).

Section 402 of BIPA, which amends section 1833(t)(6) of the Act, requires us to use categories in determining the eligibility of devices for transitional pass-through payments effective April 1, 2001. Section 1833(t)(6)(B)(ii)(IV) of the Act, as added by section 402(a) of BIPA, requires us to establish a new category for a medical device when—

- The cost of the device is not insignificant in relation to the OPD fee schedule amount;
- No existing device category is appropriate for the device; and
- Payment was not being made for the device as an outpatient hospital service as of December 31, 1996. However, section 1833(t)(6)(B)(iv) of the Act, also added by section 402(a) of BIPA, provides that a medical device may be treated as meeting these requirements if either—
 - The device is described by one of the initial categories established; or
 - The device is described by one of the additional categories established under this rule, and—
 - An application under section 515 of the Federal Food, Drug, and Cosmetic Act has been approved; or
 - The device has been cleared for market under section 510(k) of the Federal Food, Drug, and Cosmetic Act; or
 - The device is exempt from the requirements of section 510(k) of the Federal Food, Drug, and Cosmetic Act under section 510(l) or section 510(m) of that Act.

Thus, otherwise covered devices that are described by a category may be eligible for transitional pass-through payments even if they were paid as part of an outpatient service as of December 31, 1996. At the same time, no categories will be created on the basis of devices that were paid on or before December 31, 1996. Under section 1833(t)(6)(B)(iv) of the Act, no further application or approval is required for a covered device that is described by a category to qualify for a transitional pass-through payment.

Section 1833(t)(6)(B)(i)(I) of the Act, as amended by BIPA, required us to establish, by April 1, 2001, an initial set of categories based on device by type in such a way that devices eligible for transitional pass-through payments under sections 1833(t)(A)(ii) and (iv) as of January 1, 2001 would be included in a category. We developed this initial set of categories in consultation with groups representing hospitals, manufacturers of medical devices, and

other affected parties, as required by section 1833(t)(6)(B)(i)(II) of the Act, as amended by BIPA. We issued the list of initial categories on March 22, 2001, in Program Memorandum (PM) No. A-01-41, which is available on our Web site, www.hcfa.gov.

As required by section 1833(t)(6)(B)(iii) of the Act, the period during which a category of devices is eligible for transitional pass-through payments is 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.

Section 1833(t)(6)(B)(ii)(III) of the Act, as amended by BIPA, requires us to establish criteria by July 1, 2001 that will be used to create additional categories. 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.

A conforming amendment made by section 402(b)(3) of BIPA revises section 1833(t)(12)(E) of the Act concerning the limitation on administrative or judicial review of the OPPS. As amended, that section now prohibits administrative or judicial review of the determination and deletion of initial and new categories. In addition to the requirement to use device categories for purposes of the transitional pass-through payments, BIPA made other changes to those payments. Section 406 of BIPA amends section 1833(t)(6)(A)(ii) of the Act to extend transitional pass-through payments to devices used for temperature monitored cryoablation, effective for devices furnished on or after April 1, 2001.

Section 430 of BIPA amends section 1861(t)(1) of the Act to expand the definition of "drugs" to include contrast agents effective for items and services furnished on or after July 1, 2001. We implemented this provision by program memorandum (Transmittal A-01-73, June 1, 2001). Thus, contrast agents have been eligible for transitional pass-through payments since that date. The amount of the pass-through payment will be determined, as for other drugs, on the basis of 95 percent of the average wholesale price less the amount determined to be already included in the payment for the associated APC.

II. Provisions of This Interim Final Rule with Comment Period

This interim final rule sets forth the criteria for establishing new 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, as amended by BIPA. The provisions relating to transitional pass-through payments for eligible drugs and biologicals remain unchanged and are not addressed in this rule (except for the change relating to contrast agents as provided in section 430 of BIPA). Similarly, the provisions relating to new technology ambulatory payment classification (APC) groups remain the same, as set forth in our April 7, 2000 final rule (66 FR 18476). We note, however, that in the proposed rule to update the hospital OPPS for CY 2002, published on the August 24, 2001 (66 FR 44702), we proposed certain changes to the criteria for eligibility for payment in a new technology APC.

A. Changes to the Criteria for Eligibility for Pass-Through Payment of a Medical Device

As noted above, in our April 7, 2000 final rule with comment period (65 FR 18480), we defined new or innovative devices using eight criteria, three of which were revised in our August 3, 2000 interim final rule with comment period (65 FR 47673-74). These criteria were set forth in regulations at § 419.43(e)(4). For the most part, these criteria will remain applicable when defining a new category for devices. That is, devices to be included in a category must meet all previously established applicable criteria for a device eligible for transitional pass-through payments. The definition of an eligible device, however, must change to conform to the requirements of the amended section 1833(t)(6)(B)(ii) of the Act.

In addition, we are clarifying our criterion that states that a device must be approved or cleared by the FDA. The approval or clearance criterion applies only if FDA approval or clearance is required for the device as specified at new § 419.66(b)(1). For example, a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with § 405.203 through § 405.207 and §§ 405.211 through 405.215 is exempt from this requirement. A device that has received an FDA IDE and is classified by the FDA as a Category B device is eligible for a transitional pass-through

payment if all other requirements are met.

B. Criteria for Establishing Device Categories

As described above in section I of this preamble, in determining the criteria for establishing additional categories, section 1833(t)(6)(B)(ii) of the Act mandates that new categories must be established for devices that were not being paid for as an outpatient hospital service as of December 31, 1996, in such a way that no device is described by more than one category and the average cost of devices to be included in a category is not insignificant in relation to the APC payment amount for the associated service. Based on these requirements, we will use the following criteria to establish a category of devices:

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

This criterion ensures that no existing or previously existing category contains devices that are substantially similar to the devices to be included in the new category. This is consistent with the statutory mandate that no device is described by more than one category.

In addition, this criterion limits the number of new categories, and consequently transitional pass-through payments, to those categories containing devices that offer the prospect of substantial clinical improvement in the care of Medicare beneficiaries. Section 1833(t)(6)(E)(iii) of the Act, as redesignated by BIPA, requires that, if the Secretary estimates before the beginning of the year that the total amount of pass-through payments would exceed a specified percentage of total program payments (2.5 percent before 2004 and no more than 2 percent thereafter), we must uniformly reduce (prospectively) each pass-through payment in that year by an amount adequate to ensure that the limit is not exceeded.

We believe it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, the need for additional payments for devices that offer little or no clinical improvement over a previously existing device is less

apparent. These devices can still be used by hospitals, and hospitals will be paid for them through the appropriate APC payment. To the extent these devices are used, the hospitals' charges for the associated procedures will reflect their use. We will use data on hospital charges to update the APC payment rates as part of the annual update cycle. Thus, the payment process will provide an avenue to reflect appropriate payments for devices that are not substantial improvements.

We will be evaluating a request for a new category of devices against the following criteria in order to determine if it meets the substantial clinical improvement requirement:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.

- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:

- Reduced mortality rate with use of the device.

- Reduced rate of device-related complications.

- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).

- Decreased number of future hospitalizations or physician visits.

- More rapid beneficial resolution of the disease process treated because of the use of the device.

- Decreased pain, bleeding, or other quantifiable symptom.

- Reduced recovery time.

As part of the application process (described below in section II.C.), we will require the requester to submit evidence that the category of devices meets one or more of these criteria. We note that the requirements set forth above will be used only for determining whether a device is eligible for a new category under section 1833(t)(6)(B) of the Act, which authorizes transitional pass through payments for categories of devices. These criteria are not intended for use in making coverage decisions

under section 1862(a)(1)(A) of the Act. We note that adoption of these criteria is consistent with the recommendation of the Medicare Payment Advisory Commission, in its March 2001 Report to Congress, that pass-through payments for specific technologies be made only when a technology is new or substantially improved.

We expect to determine which devices represent a substantial clinical improvement over existing devices by using a panel of Federal clinical and other experts, supplemented if appropriate by individual consultation with outside experts. These decisions will, in general, be based on information submitted by the requester about the clinical benefit of the devices as described in the above criteria, including, where available, evidence from clinical trials or other clinical investigations.

We believe that almost all substantial clinical improvements in technology that are appropriately paid for under the transitional pass-through provisions result in measurable improvements in care from the perspective of the beneficiary. Nevertheless, there may be some improvements in the medical technology itself that are so significant that we may wish to recognize them for separate payment even though they do not directly result in substantial clinical improvements. For example, improvements in such factors as the strength of materials, increased battery life, miniaturization, might so improve convenience, durability, ease of operation, etc., that such an improvement in medical technology might be considered as a separate factor from "substantial clinical improvement" in beneficiary care. We invite public comment on this issue and are particularly interested in learning of examples of medical technologies for which pass through payments might be appropriate even though they would not also pass a test based on substantial improvement in beneficiary outcomes.

We note that we welcome comments on all aspects of these criteria for substantial clinical improvement, and we will consider timely comments in developing a final rule. (Comments on all parts of this interim final rule with comment will be considered if they are received within 30 days after the publication of this rule.) We will continue to evaluate these criteria as we gain experience in applying them, and we will consider revisions and refinements to them over time as appropriate.

- *Cost.* We determine that the estimated cost to hospitals of the devices in a new category (including

any candidate devices and the other devices that we believe will be included in the category) is "not insignificant" relative to the payment rate for the applicable procedures. The estimated cost of devices in a category will be considered "not insignificant" if they meet the following criteria found in regulations at new § 419.66(d):

- The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service associated with the category of devices.
- The estimated average reasonable cost of devices in the category exceeds the cost of the device-related portion of the APC payment amount for the service associated with the category of devices by at least 25 percent.
- The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount determined to be associated with the device in the associated APC exceeds 10 percent of the total APC payment.

Of these three cost criteria, the latter two are unchanged from our current thresholds for individual devices (however, as discussed below, their effective date is revised). The first criterion, however, represents a change from the current threshold.

In the April 7, 2000 final rule, we provided that a device's expected reasonable cost must exceed 25 percent of the applicable APC payment for the associated service as the criterion for determining when the cost of a specific device is "not insignificant" in relation to the APC payment (65 FR 18480). In the August 3, 2000 interim final rule, we lowered the threshold to 10 percent because we believed the 25 percent limit was too restrictive based on the brand specific approach at the time (65 FR 47673; § 419.43(e)(1)(iv)(C)). However, given our payment experience over the past year using the 10 percent threshold, including our current information on the likely amount of pass-through payments in CY 2002, we believe a higher threshold is warranted. We believe that setting a higher cost threshold will ensure that new categories are created only in those instances where they are most valuable to beneficiaries and hospitals, given the overall limits on pass-through payments. That is, pass-through payments will be targeted only to those devices where cost considerations might be most likely to interfere with patient access.

We found that once we lowered the threshold to 10 percent, a very small minority (less than 10 percent) of devices that met all other criteria for the

pass-through payment were rejected on the basis of this criterion. Partly as a result, the list of devices qualified for pass-through payments increased to well over 1000 devices by the end of 2000. Although the extensive number of qualified devices allowed hospitals to receive additional payment for many devices, we have estimated that the overall pass-through payment amount for calendar year 2002 exceeds the 2.5 percent cap. Therefore, for that year, a substantial reduction in the amount of each pass-through payment as required by section 1833(t)(6)(E)(iii) of the Act, will be necessary. Thus, allowing a large number of marginally costly devices to qualify for the pass-through payment would reduce the amount of additional payment a hospital would receive for any one device. We believe raising the threshold for this criterion will benefit hospitals by focusing the pass-through payments on those devices that represent a substantial loss to the hospital. We believe this change will also preserve beneficiary access to especially expensive devices.

In addition, once a category is established, devices included in the category will be eligible for pass-through payments regardless of the cost of the device. Therefore, we believe that it is reasonable to set a higher threshold than 10 percent to establish the category. While the cost of most devices described by a category may equal or exceed the threshold we use in establishing a category, the cost of individual devices could easily fall below the threshold. Therefore, we believe that it is reasonable to use a higher threshold in establishing a category than in qualifying individual devices.

The latter two criteria for determining that the estimated cost of a category of devices is not insignificant are unchanged from those currently included in § 419.66 (as related to individual devices). As we provided in the August 3, 2000 interim final rule, we intended to apply these criteria to devices for which a pass-through payment is first made on or after January 1, 2003 (65 FR 47673). We stated that the delay would allow us sufficient time to gather and analyze data needed to determine the current portion of the APC payment associated with the devices.

Based on the outpatient claims data we are currently using for analysis, we believe that we are able, in many cases, to begin using these criteria at this time. Although the 1996 data did not provide a level of information that allowed us to determine the portion of the APC payment that was related to the device

(except in a very few cases such as pacemakers), the newer data often does provide this level of detail. Therefore we will begin using the second and third criteria for the purpose of creating categories, as described in regulations at §§ 419.66(d)(2) and 419.66(d)(3), as soon after the implementation of this final rule as we have data to do so rather than on January 1, 2003. Although in some instances the lack of specific data will prevent the application of these criteria, we do not believe that should delay our use of these criteria in those situations in which the data are available.

C. Application Process for Creation of a New Device Category

Device manufacturers, hospitals, or other interested parties may apply for a new device category for transitional pass-through payments. The application process is very similar to the process that was previously used for item-specific review of devices and that is currently used for drugs and biologicals. Details regarding deadlines and other aspects of the application process will be available on our web site, www.hcfa.gov.

We will accept applications at any time. However, we will establish new categories only at the beginning of a calendar quarter, in deference to our computer systems needs and those of our contractors and hospitals. We must receive applications in sufficient time before the beginning of the calendar quarter in which a category would be established to allow for decision-making and programming. For now, we will require that applications be received at least 4 months before the beginning of the quarter.

We may change the details of this application process in the future to reflect experience and programmatic needs. If we revise these instructions in any way, we will submit the revisions to the Office of Management and Budget pursuant to the Paperwork Reduction Act. We will also post the revisions on our web site.

D. Announcing a New Device Category

If we determine a new category is warranted, we will issue a Program Memorandum specifying a new Healthcare Common Procedure Coding System (HCPCS, formerly known as HCFA Common Procedure Coding System) code and short and long descriptors for the category. We may also include additional clarifying or definitional information to help distinguish the new category from other existing or previously existing categories. It may be necessary to redefine, or make other changes to,

existing categories to accommodate a new category and ensure that no medical device is described by more than one category, though we will attempt to keep these changes to a minimum. We will post these Program Memoranda on our web site.

We may find it necessary occasionally to correct or amend the list of (and clarifying information associated with) new categories or initial categories. We do not expect this step will be needed often, but if it is necessary, we will issue any changes in a Program Memorandum.

E. Temperature-Monitored Cryoablation Devices

Section 406 of BIPA amends section 1833(t)(6)(A)(ii) of the Act to extend transitional pass-through payments to a device of temperature-monitored cryoablation. We have implemented this provision through PM No. A-01-40, which included categories for these devices. In our regulations at new § 419.66(e)(2), we have extended the transitional pass-through payments to a device of temperature-monitored cryoablation and specify that this medical device is not subject to the cost criteria described in § 419.66(d).

F. Contrast Agents as a Drug

Section 430 of BIPA revises the definition of drugs at section 1861(t)(1) of the Act to include contrast agents, therefore making them eligible for a transitional pass-through payment. We have implemented this provision effective July 1, 2001, through PM No. A-01-73, issued on June 1, 2001. This provision does not require any changes in our regulations as we are simply including contrast agents within the definition of drugs that were not paid as hospital outpatient services before 1997.

G. Redesignations

We are redesignating and revising our regulations at § 419.43(e) relating to transitional pass-through payments for drugs, biologicals, and devices to incorporate the changes in our policy that result from this interim final rule. Paragraph (e) has been removed and redesignated as a new subpart G. (Current subpart G is redesignated as subpart H.) The new subpart G consists of the following sections:

§ 419.62 Transitional pass-through payments: General rules.

§ 419.64 Transitional pass-through payments: Drugs and biologicals.

§ 419.66 Transitional pass-through payments: Medical devices.

We are redesignating § 419.43(f), Budget neutrality, as § 419.43(e) and revising that paragraph to limit its application only to outlier adjustments. The budget neutrality provision relating to pass-through payments is now found at § 419.62(b). We are also revising § 419.60(e), Limitations on administrative or judicial review, to conform to the changes made to section 1833(t)(12)(E) of the Act by section 402(b)(3) of BIPA.

In recodifying paragraph (e), we have made additional editorial changes to existing regulations text.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent **Federal Register** document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a proposed rule in the **Federal Register** and invite public comment on the proposed rule. The proposed rule includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. We believe that, in this case, prior notice and comment procedures would be impracticable because the statute requires we issue the criteria by July 1, only slightly more than 6 months after passage of the underlying statute. This deadline does not permit completion of the full cycle of notice and comment rulemaking before the criteria are published. Furthermore, section 1833(t)(6)(B)(ii)(I) of the Act, as amended by section 402(a) of BIPA, gives explicit authority to use an interim final rule with comment period. Therefore, we find good cause to waive

the notice of proposed rulemaking and to issue this final rule on an interim basis.

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) 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 PRA 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.

Therefore, we are soliciting public comments on each of the issues for the information collection requirement discussed below.

Process and Information Required To Apply for Additional Device Categories For Transitional Pass-Through Payment Status Under the Hospital Outpatient Prospective Payment System

The application itself for additional device categories may be found at www.hcfa.gov. The application process is very similar to the process that was previously used for item-specific review of devices and that is currently used for drugs and biologicals. Details regarding deadlines and other aspects of the application process will be available on the above web site. (See also section II. Above.)

We estimate that approximately 100 entities will file an application yearly. We believe it will take each of these entities around 16 hours to gather the necessary information and fill out the application.

We have submitted a copy of this interim final rule with comment to OMB for its review of the information collection requirement described above. The requirement is not effective until it has been approved by OMB.

If you comment on these information collection requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, DHES, SSG, Attn: John

Burke, CMS-1179-IFC, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850;

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503 Attn: Allison Eydt, Desk Officer.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 Public Law 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). This interim final rule is not a major rule because we have determined that the economic impact will be negligible for the revisions related to the transitional pass-through payments for new or innovative medical devices. In addition, the budget impact related to the transitional pass-through provision has already been addressed in the outpatient prospective payment system implementing rule published on April 7, 2000 (65 FR 18530). As stated in that rule, the pass-through provision is implemented in a budget-neutral manner as required by section 1833(t)(2)(E) of the Act. Section 1833(t)(6)(E) of the Act, as amended by BBRA and redesignated by BIPA, caps the projected additional payments annually at 2.5 percent of the total projected payments for hospital outpatient services each year before calendar year 2004 and no more than 2.0 percent in year 2004 and subsequent years.

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 ranging between \$5 million and \$25 million or less annually,

depending on the particular health care industry (for details see the Small Business Administration's final rule size standards for health care at 65 FR 69432). 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 for any final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with not more than 100 beds that is located outside of a Metropolitan Statistical Area (MSA) 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 prospective payment system, we classify these hospitals as urban hospitals.

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 will 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.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This interim final rule will not have a significant economic effect on these governments or the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. This interim final rule will not have a substantial effect on States or local governments.

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

List of Subjects in 42 CFR Part 419

Health facilities, Hospitals, Medicare.

For the reasons set forth in the preamble, 42 CFR part 419 is amended as follows:

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, 13951(t), and 1395hh).

2. Section 419.43 is amended by—
A. Removing paragraph (e).
B. Redesignating paragraph (f) as paragraph (e) and revising it to read as follows.

§ 419.43 Adjustments to national program payment and beneficiary coinsurance amounts.

* * * * *

(e) *Budget neutrality.* CMS establishes payment under paragraph (d) of this section in a budget-neutral manner.

3. Section 419.60(e) is revised to read as follows:

§ 419.60 Limitations on administrative and judicial review.

* * * * *

(e) The determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under § 419.43(d) or the determination of insignificance of cost, the duration of the additional payments (consistent with subpart G of this part), the determination of initial and new categories under § 419.66, the portion of the Medicare hospital outpatient fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under § 419.62(c).

4. Redesignate Subpart G as Subpart H.

5. New Subpart G is added to read as follows:

Subpart G Transitional Pass-through Payments

Sec.

§ 419.62 Transitional pass-through payments: general rules.

§ 419.64 Transitional pass-through payments: Drugs and biologicals.

§ 419.66 Transitional pass-through payments: Medical devices.

§ 419.62 Transitional pass-through payments: General rules.

(a) *General.* CMS provides for additional payments under §§ 419.64 and 419.66 for certain innovative medical devices, drugs, and biologicals.

(b) *Budget neutrality.* CMS establishes the additional payments under

§§ 419.64 and 419.66 in a budget neutral manner.

(c) *Uniform prospective reduction of pass-through payments.* (1) If CMS estimates before the beginning of a calendar year that the total amount of pass-through payments under §§ 419.64 and 419.66 for the year would exceed the applicable percentage (as described in paragraph (c)(2) of this section) of the total amount of Medicare payments under the outpatient prospective payment system. CMS will reduce, pro rata, the amount of each of the additional payments under §§ 419.64 and 419.66 for that year to ensure that the applicable percentage is not exceeded.

(2) The applicable percentages are as follows:

(i) For a year before CY 2004, the applicable percentage is 2.5 percent.

(ii) For 2004 and subsequent years, the applicable percentage is a percentage specified by CMS up to (but not to exceed) 2.0 percent.

§ 419.64 Transitional pass-through payments: drugs and biologicals.

(a) *Eligibility for pass-through payment.* CMS makes a transitional pass-through payment for the following drugs and biologicals that are furnished as part of an outpatient hospital service:

(1) *Orphan drugs.* A drug or biological that is used for a rare disease or condition and has been designated as an orphan drug under section 526 of the Federal Food, Drug and Cosmetic Act if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(2) *Cancer therapy drugs and biologicals.* A drug or biological that is used in cancer therapy, including, but not limited to, a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, and a bisphosphonate if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(3) *Radiopharmaceutical drugs and biological products.* A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine services if payment for the drug or biological as an outpatient hospital service was being made on August 1, 2000.

(4) *Other drugs and biologicals.* A drug or biological that meets the following conditions:

(i) It was first payable as an outpatient hospital service after December 31, 1996.

(ii) CMS has determined the cost of the drug or biological is not insignificant in relation to the amount payable for the applicable APC (as calculated under § 419.32(c)) as defined in paragraph (b) of this section.

(b) *Cost.* CMS determines the cost of a drug or biological to be not insignificant if it meets the following requirements:

(1) *Services furnished before January 1, 2003.* The expected reasonable cost of a drug or biological must exceed 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(2) *Services furnished after December 31, 2002.* CMS considers the average cost of a new drug or biological to be not insignificant if it meets the following conditions:

(i) The estimated average reasonable cost of the drug or biological in the category exceeds 10 percent of the applicable APC payment amount for the service related to the drug or biological.

(ii) The estimated average reasonable cost of the drug or biological exceeds the cost of the drug or biological portion of the APC payment amount for the related service by at least 25 percent.

(iii) The difference between the estimated reasonable cost of the drug or biological and the estimated portion of the APC payment amount for the drug or biological exceeds 10 percent of the APC payment amount for the related service.

(c) *Limited period of payment.* CMS limits the eligibility for a pass-through payment under this section to a period of at least 2 years, but not more than 3 years, that begins as follows:

(1) For a drug or biological described in paragraphs (a)(1) through (a)(3) of this section—August 1, 2000.

(2) For a drug or biological described in paragraph (a)(4) of this section—the date that CMS makes its first pass-through payment for the drug or biological.

(d) *Amount of pass-through payment.* Subject to any reduction determined under § 419.62(b), the pass-through payment for a drug or biological is 95 percent of the average wholesale price of the drug or biological minus the portion of the APC payment amount CMS determines is associated with the drug or biological.

§ 419.66 Transitional pass-through payments: medical devices.

(a) *General rule.* CMS makes a pass-through payment for a medical device that meets the requirements in paragraph (b) of this section and that is described by a category of devices

established by CMS under the criteria in paragraph (c) of this section.

(b) *Eligibility.* A medical device must meet the following requirements:

(1) If required by the FDA, the device must have received FDA approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215 of this chapter) or another appropriate FDA exemption.

(2) The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part (as required by section 1862(a)(1)(A) of the Act).

(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital.

(4) The device is not any of the following:

(i) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1).

(ii) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than radiological site marker).

(iii) A material that may be used to replace human skin (for example, a biological or synthetic material).

(c) *Criteria for establishing device categories.* CMS uses the following criteria to establish a category of devices under this section:

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

(2) CMS determines that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment.

(3) Except for medical devices identified in paragraph (e) of this section, CMS determines the cost of the device is not insignificant as described in paragraph (d) of this section.

(d) *Cost criteria.* CMS considers the average cost of a category of devices to be not insignificant if it meets the following conditions:

(1) The estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.

(2) The estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.

(3) The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service.

(e) *Devices exempt from cost criteria.* The following medical devices are not subject to the cost requirements described in paragraph (d) of this section, if payment for the device was being made as an outpatient service on August 1, 2000:

(1) A device of brachytherapy.

(2) A device of temperature-monitored cryoablation.

(f) *Identifying a category for a device.* A device is described by a category, if it meets the following conditions:

(1) Matches the long descriptor of the category code established by CMS.

(2) Conforms to guidance issued by CMS relating to the definition of terms and other information in conjunction with the category descriptors and codes.

(g) *Limited period of payment for devices.* CMS limits the eligibility for a pass-through payment established under this section to a period of at least 2 years, but not more than 3 years beginning on the date that CMS establishes a category of devices.

(h) *Amount of pass-through payment.* Subject to any reduction determined under § 419.62(b), the pass-through payment for a device is the hospital's charge for the device, adjusted to the actual cost for the device, minus the amount included in the APC payment amount for the device.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 2, 2001.

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

Approved: October 19, 2001.

Tommy G. Thompson,
Secretary.

[FR Doc. 01-27658 Filed 10-31-01; 9:17 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 419

[CMS-1159-F1]

RIN 0938-AK54

Medicare Program; Announcement of the Calendar Year 2002 Conversion Factor for the Hospital Outpatient Prospective Payment System and a Pro Rata Reduction on Transitional Pass-Through Payments

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

ACTION: Final rule.

SUMMARY: This final rule announces the Medicare hospital outpatient prospective payment system conversion factor for calendar year (CY) 2002. In addition, it describes the Secretary's estimate of the total amount of transitional pass-through payments for CY 2002 and the implementation of a uniform reduction in each of the pass-through payments for that year.

EFFECTIVE DATE: This final rule is effective January 1, 2002 and applies to services furnished on or after January 1, 2002. This rule is a major rule as defined in 5 U.S.C. 804(2). According to 5 U.S.C. 801(a)(1)(A), we are submitting a report to the Congress on this rule on November 1, 2001.

FOR FURTHER INFORMATION CONTACT: Anne Tayloe, (410) 786-0600.

SUPPLEMENTARY INFORMATION:

Availability of Copies and Electronic Access

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online database through GPO Access, a service of the U.S. Government Printing Office. The Web site address is: <http://www.access.gpo.gov/nara/index.html>.

I. Background

Section 1833(t) of the Social Security Act (the Act), as added by section 4523 of the Balanced Budget Act of 1997 (BBA), Pub. L. 105-133, provided for implementation of a prospective payment system (PPS) for hospital outpatient services furnished to Medicare beneficiaries. The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Pub. L. 106-113, amended section 1833(t) of the Act to make major changes that affected the new prospective payment system. On April 7, 2000, we published a final rule with comment period in the **Federal Register** (65 FR 18434) to implement the new PPS for hospital outpatient services. The new system established payment rates for each service paid under this system using ambulatory payment classification (APC) groups. On June 30, 2000, we published a notice in the **Federal Register** (65 FR 40535) announcing a delay in the effective date of the hospital outpatient PPS (OPPS) from July 1, 2000 (as set forth in the April 7, 2000 final rule) until August 1, 2000. Therefore, OPPS became effective on August 1, 2000. The regulations implementing the payment system appear at 42 CFR part 419.

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. On November 13, 2000, we published an interim final rule with comment period in the **Federal Register** (65 FR 67798) that 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 also responded to public comments on those portions of the April 7, 2000 final rule that implemented related provisions of the BBRA and public comments on the August 3, 2000 rule.

On August 24, 2001, we published a proposed rule in the **Federal Register** (66 FR 44672) that set forth proposed changes to the OPPS to implement applicable statutory requirements, including relevant provisions of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554), enacted on December 21, 2000, as well as changes arising from our continuing experience with the system. That document described proposed changes

to the amounts and factors used to determine the payment rates for services paid under the hospital OPPS for CY 2002. These amounts and factors include the updated conversion factor, APC classifications and relative weights, wage index values, copayment amounts, and the discussion of a possible pro rata reduction to be applied to the transitional pass-through payments for certain drugs, biologicals, and medical devices.

We received approximately 400 timely items of correspondence containing multiple comments on the August 24, 2001 proposed rule. In this final rule, we will respond to those comments addressing the Secretary's estimate of the total amount of pass-through payments for CY 2002 and the need for a uniform reduction to those payments in 2002 as well as the determination of the OPPS conversion factor for CY 2002.

In a subsequent final rule to be published by December 1, 2001, we will address the remainder of the comments and include the tables necessary to calculate CY 2002 payment rates and beneficiary copayment amounts.

II. Transitional Pass-Through Payments

A. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain innovative 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; current drugs, biologicals, and brachytherapy devices used for the treatment of cancer; and current radiopharmaceutical drugs and biologicals. Transitional pass-through payments are also required for new medical devices, drugs, and biologicals 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 for any given device, drug, or biological are to be made for at least 2 years but not more than 3 years.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for drugs and biologicals eligible for a transitional pass-through payment 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) exceeds 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. Section 1833(t)(6)(D)(ii) of the Act sets the transitional pass-through payment for a medical device at the amount by which the hospital's charges, adjusted to cost, exceeds the portion of the otherwise applicable fee schedule amount (that is, the APC payment rate) that the Secretary determines is associated with the device.

B. Pro Rata Reductions

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, the applicable percentage is a percentage specified by the Secretary up to 2.0 percent. If the Secretary estimates before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments for that year to ensure that the limit is not exceeded.

In the August 24, 2001 proposed rule setting out the proposed changes for CY 2002 in the OPPS, we described the extensive data base that we have constructed in order to prepare for making an estimate of pass-through payments for 2002. This data base includes outpatient claims data submitted by hospitals for services furnished on or after July 1, 1999 and before July 1, 2000, as well as device cost and utilization data extracted from applications for pass-through status submitted by manufacturers, hospitals, specialty societies, and other entities. In their applications for pass-through status, manufacturers have supplied information on the expected cost to hospitals of devices and the procedures with which the devices are commonly used.

In the August 24, 2001 proposed rule, we indicated that the information collected to that time suggested that a significant pro rata reduction might be required for 2002 in order to meet the statutory limit on the amount of the pass-through payments. We also announced that we were considering the appropriateness of a number of possible alternative approaches that would have the effect of minimizing the amount of any potential reduction in these

payments. Finally, we presented a discussion of the methodology that we contemplate using in the development of our estimate.

We announced in the August 24, 2001 proposed rule that we were considering a number of possible approaches to different technical aspects of estimating payments. We also indicated that, as is always the case in making these types of estimates, it would be necessary to make a number of assumptions in interpreting the data. We were tentatively contemplating using the following assumptions and techniques in developing our methodology:

1. Data and Procedures for Estimation

We planned to base the estimate of 2002 pass-through expenditures on the claims we would use to set payment rates for 2002; 2001 pass-through amounts for drugs and radiopharmaceuticals; and device cost and use data from pass-through applications submitted by manufacturers, hospitals, specialty societies, and other entities. We proposed to make projections to CY 2002 on the basis of price, volume, and service-mix inflators consistent with our baseline for OPPS spending. Estimates for drugs, radiopharmaceuticals, and devices would be made separately and combined for the final projection of pass-through spending.

2. Drug Estimate

We also proposed to identify those drugs eligible for pass-through status that have been separately billed to the Medicare program on the claims that we intend to employ for the estimate. We proposed to multiply the frequency of use for each of these drugs (that is, the number of line items multiplied by the number of units billed as shown in the claims data) by its 2001 pass-through payment amount. We would determine a reasonable adjustment to account for those drugs that do not appear in the claims data. Such an adjustment might take into account the extent to which the noncoded items were classified as orphan drugs and therefore to be used infrequently.

3. Radiopharmaceutical Estimate

As in the case of the drug estimates, we proposed to identify those radiopharmaceuticals eligible for pass-through status that were separately billed to Medicare in the claims data file. We proposed to estimate expenditures for these radiopharmaceuticals directly as described above. For radiopharmaceutical drugs, we would multiply the frequency of use for each

item by the 2001 pass-through amount. We would estimate expenditures for the remaining items by using the frequency counts for all nuclear medicine procedures not billed with one of these radiopharmaceuticals.

4. Device Estimate

We proposed to estimate the transitional pass-through payments attributable to devices by linking the frequencies for all device-related procedures in the claims data file with the cost and use data supplied by the manufacturers or other entities as part of their applications for pass-through status. We proposed to match each device eligible as of January 2001 with the procedures with which it would be used. We would then calculate an average cost for each device or device package associated with a procedure.

The statute requires that we calculate transitional pass-through payments for devices by adjusting the hospital's charge for the device to cost and then subtracting an amount that reflects the device costs already included in the payment for the associated APC. As we explained in the April 7, 2000 final rule (65 FR 18481), we were not able to implement these subtractions at the time of implementation of the system. For 2001, we made these deductions for pacemakers and neurostimulators. In the August 24, 2001 proposed rule, we proposed to make these subtractions for most other devices beginning in 2002. For the purpose of doing this estimation, we proposed to deduct these amounts from each device package before multiplying that cost by the procedure frequencies.

5. Projecting to 2002

We planned to project prices and quantities in the estimates determined as above to 2002 using actuarial projections of price and enrollee volume and service increase consistent with the OPPS baseline. We then proposed to add the three separate results in an estimate of total pass-through spending.

We received over 80 comments in response to our proposal, including comments from national provider associations, hospitals, device and drug manufacturers, and their representative associations.

Comment: Many commenters expressed concern about the data and the methodology that we proposed to use in developing an estimate of pass-through spending for 2002. A number of these commenters specifically cited the lack of actual claims data under the OPPS as one major concern. Commenters doubted that claims from the period before implementation of the

OPPS would contain sufficiently accurate coding or adequately reflect utilization of pass-through items to allow us to make an accurate estimate.

Response: We believe that the outpatient claims data submitted by hospitals for services furnished on or after July 1, 1999 and before July 1, 2000 provide adequate information for use in projecting pass-through spending for 2002. These claims are the most recent outpatient data available to us, and we are also using these claims for the purpose of recalibrating the APC relative weights for 2002. These data provide useful information on the frequencies of the procedures in which pass-through items are used, as well as of the utilization frequencies of some of the pass-through items themselves (especially drugs). Claims data for the period after the implementation of the prospective payment system are not at present available for analysis. Under the best of circumstances, we would only expect data from the prior calendar year to be available. Thus, only data from the first 5 months under the OPPS (August to December 2000) might be available at this point in the update cycle. However, the extent to which these data, were they available, would offer any significant improvement for these purposes is unclear. Those claims data would not contain information on most of the devices approved for pass-through payment in 2002 because those items became eligible for payment after January 1, 2001. It would still be necessary to use a crosswalk that maps devices to procedures in order to project spending for pass-through devices in 2002.

Comment: Some commenters questioned the appropriateness of using data on cost, utilization, and coding derived from applications from device manufacturers for pass-through status in developing the estimate. These commenters specifically contended that these data were not collected for the purpose of establishing payment amounts. They also contended that the cost, utilization, and coding information were not requested in a specific format on the applications, and that this information was therefore not presented in an appropriately consistent manner for the requisite level of analysis.

Response: The assertions of the commenters are incorrect. We were aware that we would have to develop estimates of pass-through costs for the purposes of applying the statutory limit on these costs when we developed the applications for pass-through status. We also knew at that time that we needed cost data in order to apply the cost significance eligibility criteria for pass-

through status. We deliberately developed the applications in order to generate reliable information on the cost, coding, and use of devices.

We specifically requested that the following information be uniformly provided: "Current cost of the item or service to hospitals (*i.e.*, actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in-kind)." We also specifically asked applicants to identify the Healthcare Common Procedure Coding System (HCPCS) or American Medical Association Current Procedural Terminology (CPT) service codes associated with each device application. We certainly assume that the manufacturers would be reliable sources of this information. We did not derive information on utilization frequencies solely from the manufacturers' applications for pass-through status. Rather, we calculated our projections of utilization by analyzing the claims at our disposal using a crosswalk of pass-through items to procedure codes that our clinical staff developed from the information supplied by manufacturers. The crosswalk established the CPT codes and the APCs with which the particular devices are used, while the claims data provided the frequency of use for devices in those APCs.

Comment: Many commenters questioned the validity of matching items eligible for pass-through payment with the procedures with which they would be used, citing the complexity of the CPT coding system and the variety and number of pass-through items that could be associated with particular procedure codes. The commenters asserted that a crosswalk that matched pass-through items and codes would require external review and validation. One commenter expressed concern that this crosswalk could overstate the frequencies of device use, since devices may not actually be used in every procedure where they could have been used.

Response: Using the information from the applications, our clinical staff (including physicians, nurses, and coding specialists) developed the device-to-procedure crosswalk. The staff employed a rigorous process of analysis and verification in developing this crosswalk. All members of the staff reviewed each tentative assignment of pass-through items to procedures. In order to minimize the use of individual clinical judgement, the staff made final decisions only after reaching a consensus on the assignment of pass-through items to each procedure. We are confident that the crosswalk reflects an

appropriate level of analytical rigor and independent validation.

The clinical staff also followed a conservative approach in matching devices to procedures. Specifically, they assigned pass-through items only to procedures for those pass-through items that would be typically used, even if there were other procedures in which those items might occasionally be used. Moreover, the crosswalk specifically accounts for procedures where a device or devices might be used less than 100 percent of the time. We are confident that the crosswalk procedure itself has not in any way led to an overstatement of pass-through costs.

Comment: Many commenters asserted that the method described in the August 24, 2001 proposed rule is necessarily flawed because we excluded multiple service claims from the data.

Response: We use only single service claims in calibrating the APC weights because we have no way of allocating ancillary service costs among the various procedures on multiple service claims. However, for all other facets of our annual calculation of OPPS payment amounts and factors (for example, our estimate of outlier spending and resulting thresholds), we use both single and multiple service claims. Similarly, we included both single service and multiple service claims in developing our estimate of pass-through costs and the pro rata reduction. Specifically, we used both types of claims in developing the count of the procedures associated with the use of pass-through items.

Comment: Several commenters questioned whether we had provided sufficient notice of a possible pro rata reduction to comply with the requirements of the Administrative Procedure Act. These commenters contended that the description of the proposed method for calculating a pro rata reduction was too general to allow for adequate public comment and that the data supporting the need for such a reduction should have been published to allow for public review and analysis. One commenter argued that a pro rata reduction cannot be implemented legally without specifying the size of the reduction in a proposed rule with an adequate comment period. A commenter from the drug industry stated that data on utilization should be released in time for review and analysis so that the industry could have sufficient opportunity to assess the contribution of its products to pass-through spending and to develop options and recommendations for legislative and administrative action.

Response: At the time the August 24, 2001 proposed rule was published, we had assembled a data base and developed a preliminary methodology for making an estimate of pass-through spending in 2002. Our best judgment was that further review and analysis of the data and methodology were warranted before we announced a specific estimate of 2002 pass-through spending and any requisite pro rata reduction. We therefore confined our discussion in the proposed rule to the information that was then clearly known to us, namely the general methodology that we proposed to employ, and the likely magnitude of a pro rata reduction.

We believe that our description of our data sources and methodology allowed ample opportunity for substantive comment, and we did receive numerous substantive comments on both the data sources and the methodology. Furthermore, our notice that a "significant pro rata reduction could be required for 2002" provided interested parties sufficient opportunity to assess the situation and to develop options and recommendations for both legislative and administrative action. We received many comments with proposals and recommendations for administrative action, as well as proposals for possible legislative measures that commenters have urged us to bring to the attention of the Congress. (We respond to these comments below.) Finally, we note that section 1833(t)(12) of the Act provides that there "shall be no administrative or judicial review * * * of the application of any pro rata reduction * * *."

Based on the methodology described above, we estimate that the total amount of transitional pass-through payments for 2002 would exceed the limit of 2.5 percent of total spending under the OPPS. Specifically, we estimate that total transitional pass-through payments for 2002 would be about \$2.26 billion, of which about \$1.89 billion is attributable to devices and about \$0.37 billion is attributable to drugs and radiopharmaceuticals. (Of the latter number, radiopharmaceuticals account for about \$0.17 billion, and drugs account for about \$0.20 billion.) Estimated total pass-through payments would thus be approximately 13 percent of the baseline projection of \$17.5 billion in total payments (including both program and beneficiary payments) to hospitals in 2002 under the OPPS, and pass-through payments for devices are approximately 11 percent total of OPPS payments in 2002. Based on this estimate, a pro rata reduction of 80.7 percent would be required by the statute.

Many commenters recommended measures to delay or mitigate the effects of any pro rata reduction. These comments and our responses are set forth below.

Comment: A number of commenters requested a 1-year delay in implementing a pro rata reduction, citing their concerns about data limitations and methodological weaknesses as reasons for such a delay. Other commenters recommended that any pro rata reduction should be phased in over a period of several years in order to allow vendors and hospitals adequate time to adjust to the reduced payment.

Response: The statute specifically requires that, if the Secretary estimates before the beginning of a year that the amount of the pass-through payments for that year will exceed the limit, "the Secretary shall reduce pro rata the amount of each of the additional payments * * * for that year." (Emphasis added.) Therefore, we can legally neither delay the reduction until a later year nor spread the reduction over the payments for several years. We now have an estimate of pass-through spending for 2002, and we have explained above why we believe that our methodology for determining it was reasonable.

Comment: Several commenters recommended that we use the amount "reserved" for outlier payments (up to 2.5 percent of OPPS payments) to increase the amount of money available for pass-through payments in order to reduce the need for a pro rata reduction. (As we have explained in other contexts, outlier payments are financed through a prospective reduction to PPS rates. We do not "set aside" money in a discrete fund to pay for outliers, and the same is true for pass-through payments.) Another commenter advocated that we fold the pass-through payments into the outlier "pool," and pay for the high costs of new technology as part of our payment for high cost services of all types. Other commenters contended that the 2.5 percent limit on pass-through payments was inadequate to pay for the costs of new technologies and recommended that the limit be raised.

Response: The statute provides for both the outlier and transitional pass-through payments and establishes the 2.5 percent limits on those payments for the years before 2004 (when the limit for outliers increases to 3.0 percent and the limit for transitional pass-throughs decreases to 2.0 percent). Thus, we do not have the administrative authority to make any of the changes that these commenters have recommended.

Rather, legislative action would be required to make any of these changes.

Comment: One commenter recommended that we move the procedures associated with pass-through items to the inpatient list so that they can be paid under the hospital inpatient PPS.

Response: We believe that the commenter is confused about the purpose of the inpatient list. The inpatient list identifies procedures that may not be paid under the OPPS. If medically necessary, any procedure, including those not on the inpatient list, that is performed in an inpatient setting may be paid under the hospital inpatient PPS. We decide which procedures are included on the inpatient list on the basis of clinical criteria alone. We believe that procedures should not be included on the inpatient list for payment reasons.

Comment: Several commenters asserted that a pro rata reduction will be necessary in 2002 only because we have failed to implement the transitional pass-through program as the Congress intended it. Specifically, these commenters contended that we have failed to restrict the pass-through payments to the incremental costs of new technologies by identifying the costs for predecessor technologies that are already represented in the APC payment rates and subtracting those amounts from the pass-through payments, as contemplated by the statute.

Response: Because of constraints on our data analysis before implementation of the pass-through provision, we did have difficulty initially in determining appropriate offsets for the technology costs already represented in the payment rates for many APCs. However, in the August 24, 2001 proposed rule, based on the updated claims data, we proposed appropriate offset amounts for 25 APCs that are associated with the use of pass-through devices. We will announce our final computations of the offset amounts for the affected APCs in a subsequent rule, which will be published before the beginning of the year. We will thus have substantially accounted for the technology costs that are already represented in APC payment rates, and, therefore, the magnitude of the pro rata reduction cannot be attributed to a failure to restrict pass-through payments to the incremental costs of new technology.

Comment: Many commenters expressed their concern about the prospect for a significant pro rata reduction, and the potential effect of such a reduction on access of Medicare beneficiaries to necessary treatments in

the outpatient setting. These commenters therefore urged us not to implement a pro rata reduction in 2002.

Response: A significant pro rata reduction could affect the availability of improved medical technology for Medicare beneficiaries, but the possibility of such a result is inherent in the statutory scheme. The Congress has set up a scheme to limit the aggregate amount of (projected) pass-through payments in a given year, including a requirement for a pro rata reduction. The statute reflects a balance of competing considerations—providing pass-through payments for new technologies but limiting the aggregate amount of those payments so that payments for other services are not reduced significantly (if there were no limit on projected pass-through payments, then, other things being equal, we would be reducing the base payments by 13 percent rather than 2.5 percent to ensure budget neutrality). In order to promote access to new technologies, we have decided to take a significant administrative action in order to reduce the size of the reduction. That action, which incorporates a portion of the pass-through costs into the base APCs, is discussed below. We believe that there are no other feasible and prudent administrative options available to reduce the amount of a pro rata reduction.

Comment: Several commenters, including device manufacturers and the associations that represent them, recommended that we fold the costs of pass-through devices into the base APC rates. These commenters noted that such a step would limit pass-through payments to the incremental costs of new technologies, and at least reduce the size of a pro rata reduction. Some of these commenters urged us not to implement any pro rata reduction until we have revised the base rates to include these costs.

Response: The transitional pass-through payment provision was intended as an interim measure to allow for adequate payment of new, innovative technology while we collected the necessary data to incorporate the costs for these items into the base APC rates. The statute and regulations specifically limit the payment for individual pass-through items to at least 2 years but no more than 3 years, with the intention that the costs for these items should be incorporated into the APC rates for the procedures associated with these items after that period. We agree with these commenters that we have the discretion to fold some of these costs into the APC rates before the time period for

transitional payment of specific devices has expired. (We cannot fold all of the current pass-through costs into the APC rates at this time, because the statute implies that pass-through payments for devices that have been eligible for less than 2 years must continue to be made.)

We also agree with the commenters that it is reasonable and prudent to incorporate some of the pass-through costs into the APC rates now, before we are legally required to do so, in order to mitigate the effects of the significant pro rata reduction that is mandated by the statute. Prudence also dictates, however, that we take into account all the other effects of incorporating these costs into the base rates at this time in deciding how much of the costs to incorporate into the base rates for 2002.

In addition to reducing the size of the pro rata reduction, incorporating a portion of the cost of pass-through devices into the basic APC costs has an effect on the APC relative weights. This is because the costs to be incorporated are not evenly distributed among the APCs, but are rather concentrated in a relatively small number of APCs that include the procedures that use pass-through devices. The effect of incorporating pass-through costs into the APCs is thus to decrease the APC weights for services such as clinic visits, preventive care, and diagnostic tests, while the weights for the APCs into which the pass-through costs are incorporated generally increase, often by large percentages.

In addition, increases in the relative weights for some APCs can lead to increases in beneficiary copayments because, by statute, the coinsurance rate cannot be less than 20 percent of the payment rate for an APC. We note, however, that beneficiaries are protected from much of this increase on an individual APC basis because section 1833(t)(8)(C) of the Act limits the copayment for a procedure performed in a year to no more than the amount of the inpatient hospital deductible for that year. For CY 2002, that amount is \$812.

Accordingly, choosing a percentage of the estimated pass-through costs for devices to fold into the APCs associated with the use of those devices requires us to balance several considerations. We must be mindful not only of the effect on transitional pass-through payments for drugs and devices, but also on the payments for other services and on beneficiary copayments. In addition, we note that, in CY 2003, almost all of the items currently receiving transitional pass-through payments will have reached the end of their eligibility for this payment status, and their costs must be folded into the APCs at that

time. Changes made in CY 2002 will thus provide a transition to rates in CY 2003. After weighing these factors, and considering the potential impacts of a variety of options, we have concluded it is appropriate to incorporate 75 percent of the estimated pass-through costs for devices into the procedure APCs associated with these devices. We are incorporating 75 percent of the device pass-through payments, or approximately \$1.4 billion, into the costs that are used to establish the APC relative weights for 2002.

We are not incorporating any of the current drug and biological pass-through costs into the APCs for two reasons. First, the costs for drugs and biologicals are already incorporated to a large extent into a base APC rate. As discussed more fully in the August 24, 2001 proposed rule (66 FR 44701), we assume that, for most drugs, 68 percent of the AWP is acquisition costs of the drug or biological that is already recognized in the base costs. Thus, the pass-through payment for those drugs and biologicals is 27 percent of the AWP. Second, it is generally not feasible to determine which APCs are associated with the use of drugs and biologicals from our current claims data. Unlike devices, which are used solely in the performance of certain procedures, drugs and biologicals can be provided in connection with almost any outpatient service. Thus, we are postponing the incorporation of these costs until we have data that allow us to determine the APCs with which the use of these items is associated. We note, however, that the pro rata reduction will be applied to the pass-through payment for drugs and biologicals as well as devices.

To incorporate 75 percent of the device payments, we are employing the following methodology. We use the crosswalk that we developed as part of the methodology for estimating total pass-through spending as the basis for determining the device costs that we include in setting the relative weight for each APC. As we have discussed above, this crosswalk matches devices to the typical procedures in which they are used.

In developing the total pass-through estimate, we used this crosswalk to produce a device package for each CPT code associated with device use, based on the device or devices used in each procedure included in an APC. We adjusted the costs of each package by subtracting the device costs already represented in the payment amount for the APC. (These are the costs that we deduct from each pass-through payment to ensure that the pass-through payments are limited to the incremental

costs of the new technologies. The principle for making this subtraction is the same in each case: to avoid double-counting costs already represented in the APC rates.) We then add 75 percent of these adjusted costs of the package to the costs at the claim level for each device-related procedure in the APC. At this point, we determine a revised median cost for the APC. That new median cost in turn is the basis for the APC's new relative weight.

The costs folded in will affect the relative weights of the APCs. The resulting APC payment rates will not increase on a dollar-for-dollar basis with the device costs folded into the APCs. In most cases, the device costs folded into an APC will not be uniformly distributed among the procedures in that APC. This is because procedures in an APC may require different types or numbers of devices and some procedures may not require devices at all. Therefore, the increase in median cost for an affected APC is unlikely to exactly equal the amount of the cost folded in. Furthermore, the statute requires that APC recalibration and reclassification changes be made in a manner that assures that aggregate payments will be neither greater nor less than they would have been without the changes. Changes in an APC's payment rate therefore cannot be expected to vary on a dollar-for-dollar basis with changes in the costs used to determine the APC's relative weight.

Finally, we note that the initial payments under the OPSS were calculated to be budget neutral to the methodology in use before the implementation of the OPSS. The prior payment methodology paid hospitals, on average, approximately 83 percent (the actual payment-to-cost ratio under the prior system) of their costs for furnishing outpatient services. Under the pass-through payment methodology, eligible devices are paid at 100 percent of their costs. Once these costs are incorporated into the APCs, they will also be paid at rates calculated to reflect these reductions.

The increase in APC rates due to the incorporation of these pass-through costs will be offset against the estimated 2002 pass-through payments. (As discussed above, we subtract the amount of the pass-through costs represented in the rate for the associated APC from each pass-through payment.) The remaining amount of estimated pass-through spending for 2002, once we have applied these offsets, will be subject to the pro rata reduction. Because we have not completed the recalculation of the adjusted APC payments, we are unable to provide the

specific amount of the pro rata reduction at this time. We will announce the exact amount of the reduction that will be required before the beginning of 2002. In the meantime, we are announcing that we expect the required reduction will be in the range of 65 to 70 percent. As can be seen from this estimate, folding in 75 percent of the device costs into the APCs does not reduce the pro rata by 75 percent. The following is a simplified illustration of the process.

Example: Assume there is only one device eligible for a pass-through and only one associated APC. That APC has a payment rate of \$3,000, of which \$1,000 is associated with device costs already in the APC. If a hospital bills a device with that APC whose charge adjusted to cost is \$9,000, the payment for the pass-through is \$9,000 minus \$1,000, or \$8,000. Thus, the payment for the entire service is \$3,000 for the base APC and \$8,000 for the device, for a total payment of \$11,000. The pro rata reduction would be applied to the \$8,000. If we were to implement the 80.7 percent reduction, the total payment would be \$4,544 (\$3,000 + \$8,000 (0.193)).

For the 75 percent fold-in, we would first adjust the \$9,000 device cost to account for the \$1,000 in device costs already represented in the APC rate. The remaining \$8,000 represents the adjusted costs for the device. We would then incorporate \$6,000 of the \$8,000 in adjusted costs into the APC rate. As discussed above, the increase in the APC rate is not a dollar-for-dollar match with the amount folded in. Therefore, assume that the APC rate increases by \$3,500, for a total of \$6,500. The \$6,500 payment rate now reflects \$4,500 in device costs “ the original \$1,000 plus the difference between the original APC payment (\$3,000) and the APC payment rate after the fold-in (\$6,500), or \$3,500. The increase in the amount of device costs reflected in the APC is a dollar-for-dollar match with the increase in the payment rate. The total payment for the service is now \$6,500 for the base APC and \$4,500 for the device (\$9,000 minus \$4,500), for a total payment of \$11,000. Even though 75 percent of the \$8,000, or \$6,000, has been folded into the APC rate, the pass-through payment (before any pro rata reduction) is reduced by only \$4,500, to \$4,500. Thus, folding in 75 percent of the device costs does not reduce the total pass-through estimate by that same 75 percent. However, any remaining pro rata reduction would be applied only to the \$4,500. Based on an expected reduction of between 65 and 70 percent, total payment would be between \$8,075 and \$7,850, respectively.

Comment: Several commenters requested that we clarify how the incorporation of pass-through costs into

the associated APCs would affect the APC payments. Specifically, some of these commenters requested that we clarify whether there would be a dollar-for-dollar match between the costs incorporated into an APC and the resulting increase in the APC's rate. Others asked whether there would be a dollar-for-dollar match between the increase in the APC's rate and the increase in the reduction in the pass-through payments to account for the device costs incorporated into the APC.

Response: As discussed in the response immediately preceding, there is not a dollar-for-dollar match between the costs incorporated into an APC and the resulting increase in the APC's payment rate. There is, however, a dollar-for-dollar match between the increase in an APC's rate and the increase in the reduction for the pass-through payment for devices associated with that APC. This is because the additional payment for a pass-through item equals the amount by which the hospital's cost for the item exceeds the portion of the applicable APC payment amount that is associated with the item. There is thus necessarily a dollar-for-dollar match between the increase in the APC's rate that is due to the new costs being incorporated into the APC, and the reduction applied to the pass-through payments.

Comment: Several commenters made specific requests for data files and other information related to any possible pro rata reduction. These requests included the following:

- The data files used to estimate pass-through spending, including claims data from the period July 1, 1999 and July 1, 2000.
- A comprehensive description of the methods used to identify gaps in the reporting of drugs, biologicals, and devices, and the assumptions used to estimate utilization of pass-through items.
- An estimate of projected pass-through payments for 2002, including breakdowns by category (orphan drugs, cancer drugs, devices, etc.).
- An estimate of the magnitude of any proposed reduction in pass-through payments to meet the 2.5 percent statutory cap.
- A detailed description of how any pro rata reduction would be implemented.

Response: It is our general practice to release the data we use in setting Medicare payment amounts to the public when we announce proposed payment amounts. Some of the data requested by these commenters, especially the relevant claims data for the period July 1, 1999 and July 1, 2000,

were in fact released at the time of the August 24, 2001 proposed rule because these data were used in developing the proposed APC payment rates in that rule. We did publish a substantive description of the methodology that we were proposing to use in developing an estimate of pass-through costs, and we received numerous comments on that proposed methodology. To the degree that we did not release some of the other information requested by these commenters, such as an estimate of a proposed pro rata reduction and a breakdown of pass-through costs by category, it was because we were still reviewing our methodology and analyzing the data. We did, however, present the public with the likely magnitude of a reduction at that time.

In this final rule, in response to the comments, we are providing more information on the methodology that we have used to determine the pro rata reduction. We are also providing a detailed account of our calculation of 2002 pass-through costs. We plan to release additional information when we announce the exact percentage of the required pro rata reduction before the beginning of the year. The pro rata reduction will be implemented by our systems as a uniform reduction to every pass-through payment.

Comment: The Medicare Payment Assessment Commission commented that the transitional pass-through provision has three flaws:

- The use of categories to determine the eligibility of devices allows devices the costs of which had already been taken into account in setting the base rates to qualify for pass-through payments.
- The pass-through payments for drugs and biologicals are set at 95 percent of average wholesale cost, thus creating an incentive to increase Medicare payments by raising prices for these items.
- Pass-through payment rates are based on hospital-specific cost-to-charge ratios, allowing hospitals to increase their payments by raising the charges for eligible items.

The Commission recommended that the Congress enact three statutory changes to improve the transitional pass-through provision:

- Restrict the eligibility for pass-through payments to technologies that are new or substantially improved and that add substantially to the cost of care.
- Allow for the costs of pass-through items to be completely incorporated into the base APC rates more quickly than the current statutory eligibility period of 2 to 3 years allows.

• Replace the facility-specific payments for devices with national payments.

Response: We appreciate the Commission's comments about flaws in the transitional pass-through provision. We will be available to provide technical assistance to the appropriate congressional committees in developing measures to improve the provision. We do note, however, that although the use of categories allows devices whose costs had previously been included in the calculation of the APC payment rates to qualify for pass-through payments, those payments will be reduced by the amount that we have calculated to be reflected in that APC. However, this subtraction of the costs in the APC may not reduce the pass-through payment for those devices to zero.

III. Conversion Factor Update for CY 2002

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, as redesignated by section 401 of the BIPA, provides that for 2002, 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, reduced by one percentage point. Further, section 401 of the BIPA increased the conversion factor for 2001 to reflect an update equal to the full market basket percentage increase amount.

To set the proposed OPPS conversion factor for 2002, we increased the 2001 conversion factor of \$50.080, which reflects the BIPA provision of the full market basket update, by 2.3 percent, that is, the full market basket percentage increase of 3.3 percent minus 1 percentage point.

In accordance with section 1833(t)(9)(B) of the Act, we further adjusted the conversion factor for 2002 to ensure that the revisions we made to update the wage index are made on a budget-neutral basis. A proposed budget neutrality factor of 0.9924 was calculated for wage index changes by comparing total payments from our simulation model using the proposed FY 2002 hospital inpatient PPS wage index values to those payments using the current (FY 2001) wage index values.

The increase factor of 2.3 percent for 2002 and the required wage index budget neutrality adjustment of 0.9924 resulted in a proposed conversion factor for 2002 of \$50.842.

Based on the 2.3 percent update factor and the final FY 2002 hospital inpatient

wage index values, the final wage index budget neutrality adjustment is 0.9936, which results in a final conversion factor for 2002 of \$50.904.

We received one comment on the calculation of the conversion factor.

Comment: One commenter requested clarification of the methodology used to calculate the conversion factor for CY 2002, particularly as it relates to the payment update provided by section 401 of BIPA. The commenter is concerned that we did not explain that the CY 2001 conversion factor we set forth in the August 24, 2001 proposed rule as the basis for the CY 2002 conversion factor was never used to make payment in CY 2001.

Response: Before the enactment of BIPA on December 21, 2000, section 1833(t)(3)(C)(iii) of the Act provided for a 2001 update of the market basket percentage increase reduced by 1 percentage point. This is the update that was implemented by the November 13, 2000 final rule (65 FR 67827).

Section 401(a) of BIPA amended section 1833(t)(3)(C)(iii) (redesignated by section 401(b) of BIPA as section 1833(t)(3)(C)(iv)) of the Act to provide for a full market basket percentage increase for CY 2001. However, section 401(c) of BIPA also provided a special payment rule for CY 2001 that requires the payment rate for services furnished under the OPPS on or after April 1, 2001 and before January 1, 2002 to be updated by an additional 0.32 percent to account for the timing of the implementation of the full market basket update for 2001. Thus, the conversion factor used to make payment on or after January 1 and before April 1, 2001 was based on a market basket percentage increase minus 1 percentage point, and the conversion factor used to make payment on or after April 1, 2001 was based on a full market basket percentage increase increased by 0.32 percent. Payment was never made in 2001 using a conversion factor based on a full market basket percentage increase. However, it is this last conversion factor (which is equal to \$50.080) that must be used to update the conversion factor for CY 2002.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

V. Regulatory Impact Analysis

A. General

We have examined the impacts of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 Public Law 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).

The statutory effects of the provisions that are implemented by this final rule result in expenditures exceeding \$100 million per year. We estimate the total impact of these changes for CY 2002 payments compared to CY 2001 payments to be approximately a \$400 million increase. Therefore, this final 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 \$5 to \$25 million or less annually (see 65 FR 69432). For purposes of the RFA, all providers of hospital outpatient services are considered small entities. 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 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area (MSA) and has fewer than 100 beds, or New England County Metropolitan Area (NECMA). Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21) designated hospitals in certain New

England counties as belonging to the adjacent NECMA. Thus, for purposes of the OPPS, we classify these hospitals as urban hospitals.

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

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 one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This final rule does not mandate any requirements for State, local, or tribal governments.

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 final rule in accordance with Executive Order 13132, Federalism, and have determined that it will not have any negative impact on the rights, roles, and responsibilities of State, local, or tribal governments.

B. Changes in This Final Rule

This final rule implements 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. In addition, section 1833(t)(6)(E)(iii) of the Act requires a uniform reduction in the amount of each of the transitional pass-through payments made in a year if the Secretary estimates, before the beginning of that year, that the total pass-through payments will exceed an applicable percentage of total payments estimated to be made under OPPS in that year. For CY 2002, the applicable percentage is 2.5 percent.

The projected aggregate impact of updating the conversion factor is to increase total payments to hospitals by 2.3 percent. As described in the preamble, a budget neutrality adjustment is made to the conversion factor to assure that the revision in the wage index does not affect aggregate payments.

C. Estimated Impacts of This Final Rule

The 2.3 percent update in the conversion factor results, in the

aggregate, in an increase in payments for hospitals under the OPPS of approximately \$400 million.

As discussed above in section II of this preamble, we have estimated that the total amount of pass-through payments for CY 2002 would be \$2.26 billion if we did not fold in costs of pass-through devices into the base APC rates. Of that amount, approximately \$0.37 million represents payments for drugs and biologicals and \$1.89 billion represents payments for medical devices. Total OPPS payments in CY 2002 are estimated to be \$17.5 billion. Because the estimate of pass-through payments exceeds 2.5 percent of estimated total payments, which is approximately \$437 million (2.5 percent of \$17.5 billion), we must implement a uniform reduction of all pass-through payments. Absent any administrative action, the estimate of the reduction necessary to account for the full pass-through estimate would be 80.7 percent. That is, we would pay 19.3 percent of the otherwise applicable pass-through payment for drugs, biologicals, and devices.

As further discussed above in section II of this preamble, in order to mitigate the effects of this significant pro rata reduction, we are incorporating, into the base APC costs, 75 percent of the cost of the devices currently eligible for pass-through payment. In the proposed rule, we estimated for most APCs that involve devices, an amount that represents the cost of devices already included in the APC payments. Those amounts would be subtracted from any pass-through payments associated with those APCs (before the pro rata reduction). That policy reduced the total estimate of pass-through payments by approximately \$450 million. Because we are now incorporating additional device costs into the base APC costs, those subtraction amounts will increase to reflect the additional amounts included in the device-related APC payments. Thus, the total amount of pass-through payments estimated to be made in CY 2002 will be reduced, which will, in turn, reduce the amount of the pro rata reduction necessary to meet the 2.5 percent limit. As noted above in this preamble, because we have not yet completed our analysis and computations related to the fold in, we cannot yet announce the exact size of the pro rata reduction. However, we estimate that the amount of the reduction will be between 65 and 70 percent. The incorporation of costs into the base APCs results in the pro rata reduction being applied only to the marginal costs of the pass-through devices not incorporated into the APCs.

We believe that the changes we have made in this final rule will lessen the impact on hospitals of the required pro rata reduction on pass-through payments.

We estimate that the implementation of the pro rata reduction on pass-through payments for devices will affect urban hospitals more than rural hospitals and, in urban areas, large urban and teaching hospitals will be affected more than other urban hospitals. This is due to the fact that the types of outpatient procedures that use the pass-through devices are more frequently performed in large urban hospitals, particularly teaching hospitals. We estimate that the effect of the reduction on pass-through payments for drugs and biologicals may be more uniform across types of hospitals. Use of these items is more widespread among hospitals, although hospitals that furnish chemotherapy may be affected to a greater degree than others.

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

List of Subjects in 42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR part 419 is amended as follows:

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).

2. In § 419.62, paragraph (c) is republished and a new paragraph (d) is added to read as follows:

§ 419.62 Transitional pass-through payments: General rules.

* * * * *

(c) *Uniform prospective reduction of pass-through payments.* (1) If CMS estimates before the beginning of a calendar year that the total amount of pass-through payments under §§ 419.64 and 419.66 for the year would exceed the applicable percentage (as described in paragraph (c)(2) of this section) of the total amount of Medicare payments under the outpatient prospective payment system. CMS will reduce, pro rata, the amount of each of the additional payments under §§ 419.64 and 419.66 for that year to ensure that the applicable percentage is not exceeded.

(2) The applicable percentages are as follows:

(i) For a year before CY 2004, the applicable percentage is 2.5 percent.

(ii) For 2004 and subsequent years, the applicable percentage is a percentage specified by CMS up to (but not to exceed) 2.0 percent.

(d) *CY 2002 incorporated amount.* For CY 2002, CMS incorporated 75 percent

of the estimated pass-through costs (before the incorporation and any pro rata reduction) for devices into the procedure APCs associated with these devices.

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

Dated: October 30, 2001.

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

Approved: October 26, 2001.

Tommy G. Thompson,
Secretary.

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