

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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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, 1395l(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.

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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:
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SUPPLEMENTARY INFORMATION:

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