Supporting Statement For Paperwork Reduction Act
Information Collection for Transitional Pass-through Payments
Related to Additional Medical Device Categories
Under the Outpatient Prospective Payment System
And Supporting Regulations in 42 CFR Part 419
(Refer to the following:
http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/catapp.pdf and Federal Register rules of November 2, 2001 and November 1, 2002)

A. Background

Since implementation of the hospital outpatient prospective payment system (OPPS), effective August 1, 2000, transitional pass-through payments have been made to hospitals for certain drugs, biologicals, and medical devices. These are temporary additional payments required by section 1833(t)(6) of the Social Security Act (the Act), which was added by section 201(b) of the Balanced Budget Act of 1999 (BBRA). The law required the Secretary to make these additional payments to hospitals for at least 2 but no more than 3 years. The items designated by the law are as follows:

- Current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act;
- Current drugs, biologic agents, and brachytherapy devices used for the treatment of cancer;
- Current radiopharmaceuticals and biological products;
- New medical devices, drugs, and biologic agents if the item was not being paid for as a hospital outpatient service as of December 31, 1996, and if the cost of the item is "not insignificant" in relation to the hospital outpatient PPS amount.

For those drugs, biologicals, and devices referred to as "current," the transitional pass-through payment begins on the first date the new OPPS is implemented, as required by section 1833(t)(6)(B)(i) of the Act.

We set forth the criteria that we would apply to determine which medical devices were eligible for transitional pass-through payments in the April 7, 2000 final rule with comment period (65 FR 18434) that implemented the new OPPS. In that rule, we also discussed the three cost tests that we would apply to determine a new item's eligibility for transitional pass-through status. In addition, we described the application process that we would use to determine transitional pass-through status and the process that we would use to promptly assign "C" codes of the Healthcare Common Procedure Coding System (HCPCS) to all eligible items for billing if no national codes have been assigned.

In addition, we posted the application process on our web site at **www.cms.hhs.gov**. Items were only considered eligible for payment if we listed them in one of a number of lists published in Medicare Program Memoranda and posted to our web site. We established a quarterly application process by which interested parties could submit applications to us for particular items. Each item had to qualify for pass-through status based on its individual

characteristics and not on its similarity to other eligible items. Consequently, from implementation of OPPS through March 31, 2001, we determined over 1,500 devices, more than 200 drugs, and about 40 biologicals were eligible for transitional pass-through payments.

On August 3, 2000, we published an interim final rule with comment period in the Federal Register (65 FR 47670) in which we modified the medical device criteria, revised one of the three cost significance tests for new items, and delayed implementation of the other two. These criteria are compiled in 42 CFR 419.66. They were made final in the November 13, 2000 interim final rule with comment period (65 FR 67798) that updated the OPPS for 2001.

Section 402 of the Benefits Improvement and Protection Act of 2000 (BIPA), enacted on December 21, 2000, made changes in the provision for transitional pass-through payment for devices under the hospital OPPS. Section 402 of BIPA amended section 1833(t)(6) of the Act to require that we abandon the item-specific approach in determining the eligibility of medical devices for transitional pass-through payments. This provision mandated that we adopt a category approach for making such payments. In accordance with this requirement, we would pay for any device that falls in categories we establish for this purpose. This provision required us to establish the initial set of categories, to include devices previously determined eligible for transitional pass-through payments, effective April 1, 2001.

We established 96 initial categories and announced them in a Medicare Program Memorandum (Transmittal A-01-41) issued March 22, 2001. Two more initial pass-through categories were added by means of Program Memorandum (Transmittal A-01-73) issued June 1, 2001. While the initial categories are based only on devices that were determined eligible for transitional pass-through payments on an item-specific basis, other devices that were not previously qualified also fit in these categories if they meet conditions set forth in Transmittal A-01-41, without the need to make application. The categories are mutually exclusive as required by law. Under BIPA, we are also required to establish criteria that will be used to create additional categories for new devices not described by the initial categories, to be implemented through the rulemaking process by July 1, 2001. In addition, BIPA eliminated the application or approval process for an individual device that fits within the description of any category. Further, BIPA required that the test for whether the cost of a device is "not insignificant" be applied in determining eligibility of an entire category, not to an individual device. We note that section 402 of BIPA did not modify the transitional pass-through provisions applicable to drugs and biologicals.

The transitional pass-through provision provides a way for ensuring appropriate payment for new technologies whose use and costs are not adequately represented in the base year claims data on which the outpatient PPS is constructed as required by law. Categories of medical devices will receive transitional pass-through payments for 2 to 3 years from the date payments are initiated for the category. However, the underlying provision is permanent and provides an on-going mechanism for reflecting timely introduction of new items into the payment structure. We note that transitional pass-through payments for the initial categories of medical devices expired as of January 1, 2003 because the categories encompass many medical devices that obtained pass-through status in 2000. However, pass-through payment

for new device categories added subsequently would continue for 2 to 3 years from the time they were first paid.

Actual hospital cost data gathered during the 2 to 3 years hospitals are paid pass-through payments for devices are used to appropriately assign the costs of the pass-through devices to existing outpatient payment groups referred to as “ambulatory payment classifications” or APCs, which are clinically related payment groups with comparable resource costs. For example, the costs related to the initial categories which expired from pass-through payment, were included in the applicable clinically related APCs, simultaneous with the expiration of those categories’ pass-through payments.

The April 2000 final rule also defined a special category of APCs referred to as “New Technology APCs” for certain innovative services. We assign services to the New Technology APCs that we determine cannot be placed appropriately in regular APCs. As we indicated in our previous PRA submissions, because of the BIPA provisions requiring categories of devices (described above) and the differences between the pass-through criteria and the criteria for eligibility and application information requested for New Technology APC assignment, we submitted separate PRA clearance packages for each of these special payment mechanisms that require an application process. Therefore, we will continue to describe the New Technology APC and the drugs and biologicals pass-through processes in greater detail in separate PRA submissions. This document addresses the application process for additional transitional pass-through device categories.

Since the time that we published our application process and criteria for new device categories for pass-through payment on November 2, 2001 pursuant to BIPA, we have received and processed 107 new device category applications, through June 1, 2007. We accept applications on a continuous basis, with quarterly benchmark “deadline” dates in order to evaluate and process the applications for payment by the next available quarter, if warranted and if possible. We initially received approximately 20 applications for each of the first two quarters after we published the application process related to additional device categories. Subsequently, the number of applications has decreased to the current rate of approximately 1 to 3 per quarter. To this point, 13 new device categories have been created for transitional pass-through payment. Prior to the device category process mandated by BIPA, we qualified more than 1700 brand-specific items for transitional pass-through payments through our application process. (After the passage of BIPA, the brand-specific devices were assigned to and paid under the 98 initial categories, beginning April 1, 2001.)

To keep pace with emerging new technologies and make them accessible to Medicare beneficiaries in a timely manner as the law intended, it is necessary that we continue to collect appropriate information from interested parties such as hospitals, reimbursement consultants, and device manufacturers that bring to our attention specific new categories of medical devices that they wish us to evaluate for transitional pass-through payment status.

On November 2, 2001, we published an interim final rule that sets forth the criteria we have used to establish new categories of medical devices eligible for transitional pass-through payments under the OPPS. These criteria were made final in our November 1, 2002 final rule

(67 FR 66781). These rules are attached as part of this filing. We also modified two of the criteria for eligibility to establish new device categories for pass-through payment in our November 10, 2005 interim final rule. However, the application process and requirements were not changed in that rule, and remain the same as in the 2001 and 2002 final rules just referenced.

B. Justification

1. Need and Legal Basis

As stated above, section 201(b) of the BBRA 1999 amended section 1833(t) of the Act by adding new section 1833(t)(6). This provision requires the Secretary to make additional payments to hospitals for a period of 2 to 3 years for certain drugs, radiopharmaceuticals, biological agents, medical devices and brachytherapy devices. Section 1833(t)(6)(A)(iv) establishes the criteria for determining the application of this provision to new items. Section 1833(t)(6)(C)(ii) provides that the additional payment for medical devices be the amount by which the hospital's charges for the device, adjusted to cost, exceed the portion of the otherwise applicable hospital outpatient department fee schedule amount determined by the Secretary to be associated with the device. Section 402 of BIPA made changes to the transitional pass-through provision for medical devices. The most significant change is the required use of categories as the basis for determining transitional pass-through eligibility for medical devices, through the addition of section 1833(t)(6)(B) of the Act.

In developing criteria for new categories of devices that will be eligible for temporary pass-through payments, CMS had to balance a number of considerations. On the one hand, it is important for people with Medicare coverage to have access to new technologies, and Congress has expressed concern that Medicare payment policies not deprive beneficiaries of access to services. On the other hand, the more devices that are eligible for pass-through payments under this category rule, the more likely pass-through payments will exceed the statutory cap imposed on spending, in turn necessitating imposition of a proportionately greater pro rata reduction to pass-through payments as required by the law. In the November 2, 2001 category criteria rule, CMS opted for a high threshold of eligibility: the devices in a new category must be expected to produce substantial clinical benefit, and they must be so expensive that lack of a special payment may hinder access to these devices.

The law made clear that application and approval processes are no longer required as the basis for determining an individual medical device's eligibility for transitional pass-through payments. However, we must assemble certain crucial information to be able to determine the appropriateness of establishing an additional category. The information that we seek to collect is essential to determine whether additional categories of medical devices are appropriate for transitional pass-through payments. The intent of these provisions is to ensure that timely beneficiary access to new technologies is not jeopardized by inadequate payment levels.

2. Information Users

Interested parties such as hospitals, device manufacturers, pharmaceutical companies, and physicians apply for transitional pass-through payment for certain items used with services covered in the outpatient PPS. After we receive all requested information, we evaluate the information to determine if the creation of an additional category of medical devices for transitional pass-through payments is justified. We may request additional information related to the proposed new device category, as needed. We advise the applicant of our decision, and update the outpatient PPS during its next scheduled payment update cycle to reflect any newly approved device categories. We list below the information that we require from all applicants. This information is identical to the list of information requirements in our initial PRA submission. Following is the information required to process requests for additional categories of medical devices for transitional pass-through payments:

A. Proposed name or description for the additional category.
B. Trade/brand names of any known devices fitting the proposed additional category. (Applications must include the name and description of at least one marketed medical device, or device with a FDA Category B investigational device exemption, that would be placed in the proposed additional category.)
C. A list of all existing or previously existing categories that describe related or similar devices. For each existing or previously existing category, provide a detailed explanation as to why that category does not encompass the nominated device(s).
D. Detailed description of the clinical use(s) of each nominated device requiring an additional category.
    1. Describe each nominated device fully:
        a. What is it? Provide a complete physical description of the device including its components, e.g., hardware, software, reservoir, tubing, its composition, coating, or covering.
        b. What does it do?
        c. How is it used?
        d. What makes it different from similar devices of the same type?
        e. What are its clinical characteristics, e.g., is it used for diagnosis or treatment, what is its life span, what are the complications associated with its use, for what disease processes and patient populations is it used?
        f. Submit relevant booklets, pamphlets, brochures, product catalogues, price lists, and/or package inserts that further describe and illuminate the nature of the nominated device.
    2. Using Healthcare Common Procedure Coding System (HCPCS) Level I and/or Level II code(s), list all of the specific procedure(s) and/or services with which the nominated device is used. (HCPCS Level I is the American Medical Association’s *Current Procedural Terminology* (CPT); HCPCS Level II National Codes are alpha-numeric codes that describe medical services and supplies not contained in CPT.)
    3. If a device replaces or improves upon an existing device, identify the trade/brand name of the existing device and any HCPCS Level I and/or Level II code(s) used to identify the existing device.

4. Identify by name and manufacturer similar devices that would also become eligible for transitional pass-through payment under the proposed additional category, insofar as this information is known to the applicant.

E. Substantial Clinical Improvement:

Provide a full discussion of the reasons why the device for which an additional category is requested meets the **substantial clinical improvement** criterion that CMS uses to establish an additional category. This discussion must include evidence to demonstrate that the device under consideration satisfies one or more of the measures of "substantial clinical improvement" that are listed in the November 2, 2001 interim final rule and the November 1, 2002 final rule. This evidence can include copies of published peer-review literature and other materials to demonstrate substantial clinical improvement.

F. Sales and Marketing:

Provide the following information for the device(s) for which an additional category is proposed:

1. Date(s) the device for which an additional category is requested was first marketed--
   a. In the United States
   b. Outside the United States
2. Date of sale of first unit of the device nominated for an additional category--
   a. In the United States
   b. Outside the United States
3. Number of device(s) nominated for an additional category that have been sold up to the date of the application.
4. Number of facilities currently using the nominated device.
5. Projected total annual utilization for both the nominated device and for the proposed device category as a whole.
6. Indicate the annual projected utilization of the nominated device in connection with each HCPCS with which it is used. For example, projected utilization in connection with CPT code xxxxx equals 300 cases using 1 device per case; utilization in connection with CPT code yyyyy equals 1500 cases using 3 devices per case; utilization in connection with HCPCS code zzzzz equals 50 cases with 6 devices required per case.
7. For each CPT code associated with a device, estimate annual utilization by site of service, that is, for HCPCS code xxxxx, projected utilization is 40% hospital outpatient, 30% ambulatory surgical center, 10% hospital inpatient, 20 % physician office.

G. Cost:

Indicate the current cost of the device to hospitals, that is, the actual cost paid by hospitals for the device net of all discounts, rebates, and incentives in cash or in kind. In other words, submit the best and latest information available that provides evidence of the hospitals' actual cost for the nominated device.

H. FDA Approval:

1. If the device requires approval or clearance by the Food and Drug Administration (FDA), submit a copy of the FDA approval/clearance letter.

2. If the device has an investigational device exemption (IDE), submit the FDA approval letter and indicate whether it is a “Category B” IDE.
3. If the device is covered by a guidance document or is exempt from FDA approval or clearance, provide the complete citation of the guidance level regulation or exemption from approval or clearance.
4. If a new category of devices is exempt from FDA approval or clearance, or the FDA has chosen an alternate regulatory scheme (e.g., guidance documentation during a defined period of time), then the applicant should so state, along with supporting references and citations.

I. Contact Information: Name(s), address(es), e-mail addresses and telephone number(s) of the party or parties making the request and responsible for the information contained in the application. If different from the requester, give the name, address, e-mail address, and telephone number of the person that CMS should contact for any additional information that may be needed to evaluate the application.

3. Improved Information Technology

This collection of information does not currently involve the use of automated, electronic or other technological collection techniques.

Much of the information requested does not easily lend itself to many of the advantages of electronic collection techniques. Specifically, data items such as detailed description of the clinical application, a full discussion of reasons why a new category is needed and why the application meets the "substantial improvement criterion" lend themselves to unstructured narrative explanation rather than structured data that can be categorized into elements in a database.

Some of the data could be feasibly collected electronically. However, it does not seem efficient to collect some information electronically and other data by non-electronic means, because this would entail submitting separate parts of the application by applicants and matching the respective parts by CMS. We stated in our initial PRA submission that we would explore the feasibility of electronic submissions, especially in the event that the number of applications for new device categories far exceeds our initial estimate of 100. However, our experience has shown a much lower number of applications. Our current estimate based on our experience is 10 to 12 application per year. We therefore believe that electronic submission of information is not feasible at this time.

Because a signature on the application is not required, the acceptability of an electronic signature is not an issue.

4. Duplication of Similar Information

Some of the information contained in this collection is similar to that submitted by applicants who apply for HCPCS codes for new items. Our review process entails assigning HCPCS codes to new items. Therefore, the information serves a two-fold purpose and minimizes rather than duplicates information.

5. Small Businesses

This information collection will affect small entities such as providers of hospital outpatient services and small device manufacturers that wish to have items evaluated for additional categories for transitional pass-through payment status under the outpatient PPS. To minimize the burden, we have limited the specific information being collected solely to the essential elements necessary to make the appropriate decisions. Much of the information collected is information that is routinely developed and maintained by manufacturers seeking FDA's approval/clearance of devices, drugs, and biologicals; is used for marketing purposes; and is submitted to CMS to obtain national HCPCS codes for billing purposes. Much of this information is also readily available to hospitals through their record keeping systems.

6. Less Frequent Collection

This information is collected only as needed to comply with statutory requirements regarding the establishment of new device categories. This is not a regularly scheduled information collection. The frequency and timing of information collection is determined individually by interested parties, based on the number of items they wish to have evaluated. If we were to collect this information less frequently, CMS would not obtain the data it needs to evaluate such requests, nor would we be able to make transitional pass-through payments for devices that may be eligible for such payments.

7. Special Circumstances

There are no special circumstances associated with this collection.

8. Federal Register Notice/Outside Consultation

A 60-day Federal Register notice was published on July 20, 2007.
The November 2, 2001 Federal Register interim final rule and the November 1, 2002 final rule that set forth and made final the criteria we use to establish new categories for medical devices. These rules also reference the application requirements and are attached. The November 10, 2005 interim final rule modifies 2 of the criteria used to establish new categories for medical devices, but does not change or reference the application process and therefore is not attached.

We had numerous meetings and discussions with individual device drug and biological manufacturers, the Advanced Medical Device Manufacturers Association, Medical Manufacturers Device Association, Nuclear Medicine APC Task Force, and hospitals in response to implementing the item-specific and device category transitional pass-through provisions. Based on these discussions, our experience in processing applications and our knowledge of the requirements for FDA approval/clearance to market many of the items that have been submitted to us for review and the requirements for HCPCS codes for such items, we believe that the information we collect is readily available to the applicants.

9. Payments/Gifts To Respondents

There is no payment or gift to respondents.

10. Confidentiality

Because CMS makes information used in the ratesetting process under the OPPS available to the public for analysis, applicants are advised that any information submitted, including commercial or financial data, is subject to disclosure for this purpose.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimate (Total Hours & Wages)

Based on our recent experience, we anticipate receiving approximately 10 requests annually for additional device categories related to transitional pass-through determination. We estimate that it will take approximately 16 hours on average for an applicant to compile the information requested, with the actual time being dependent on the type of category nomination being submitted. Based on an assumption of 10 requests annually, the total burden is 16 hours (average time) X 10 requests = 160 hours.

The information for various items may be compiled by personnel at different levels of pay (clerk, lawyer, medical staff, etc.). Based on this we are using an average of salary of $50/hour to calculate the cost.

$50/hr x 16 hours (average estimated time) x 10 (estimated number of applicants)=
$8,000 total cost

13. Capital Costs

Not applicable to this collection.

14. Cost to the Federal Government

The cost to process the information submitted is estimated as follows based on review by analysts/ medical officers and supervisory staff . This review includes analyses, call backs to applicants to clarify or obtain missing information, required data calculations, database inputs and conferences with applicants and their representatives. We estimate the total time to process, evaluate and reach a decision is 40 to 60 hours per category application. We use the midpoint of this range to derive the following estimate.

$45/hr (average salary GS 13/14/15) X 50 hours/ request X 10 requests = $22,500

15. Program Changes

We are making an adjustment (i.e., not a Program Change) to our estimate of the number of total hours of Burden based on our recent experience in applications received. We are receiving fewer applications, and a therefore reducing our estimate to 10 applications per year (from 12 applications).

16. Publication and Tabulation Dates

We do not plan to publish the information collected under this submission. However, the information will be used to determine eligibility for the special transitional pass-through payment provisions of the BBRA 1999 and BIPA 2000. If a new category is determined to be appropriate, it will be included on a list of identified additional pass-through/ new technology items and device categories, which will be posted on our web site, published in the appropriate program transmittal or Federal Register notice and distributed via program transmittal to CMS contractors. CMS intends to make information used in the ratesetting process under the OPPS available to the public for analysis, which would include information related to transitional pass-through payments such as that submitted in the applications for device categories.

17. Expiration Date

This collection does not lend itself to the display of an expiration date, because it does not utilize a form. Moreover, the need for this information collection will remain in effect as long as the statute provides for the creation of additional categories of medical devices eligible for pass-though payments under the OPPS.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

Not applicable to this collection.