Supporting Statement – Part A

Recognition of Pass-Through Payment for Additional (New) Categories of Devices under the Outpatient Prospective Payment System and Supporting Regulations

(CMS-10052; OMB 0938-0857)

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.gov. 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. This criteria is compiled in 42 CFR 419.66 and was 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.

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 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). 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 (70 FR 68628). 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.

On November 20, 2009, we published a final rule with comment period in the Federal Register (74 FR 60471) that provided modifications to the pass-through process for implantable biological products. Additionally, we published additional modifications to the pass-through process for skin substitutes in the November 10, 2015 Federal Register (79 FR 66885). Furthermore, we published additional modifications to the pass-through process and the addition of a newness criterion the interim final rule with comment period in the

November 13 2015, Federal Register (80 FR 70416). Please note, the addition of a newness criterion and other aforementioned modifications did not change the application process or requirements.

To keep pace with new technology and to make this application process more efficient, we implemented an electronic application intake system called the Medicare Electronic Application Request Information System (MEARIS™) for the CMS-10052 form, which CMS required all applicants use effective March 2, 2022. Prior to March 2, 2022, applicants could choose to complete the paper application or the electronic application in MEARIS™. The application in MEARIS™ is similar to the paper application form (CMS-10052, OMB 0938-0857), except for a few minor changes to either accommodate the web format or further provide simplification or clarification of the existing application questions; we are not requiring any new information. Prior to implementing this new electronic application process, we requested and received a non-substantive change PRA approval from OMB, which expires November 30, 2022.

We are now requesting to extend this PRA for an additional 3 years. CMS will add two (2) questions to the Device pass-through application on MEARIS. The additional questions will provide more precise eligibility information to CMS earlier in the application. Adding the two (2) questions in MEARIS does not have an effect on burden.

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 had 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 (new) 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 quarterly payment update cycle to reflect any newly approved device categories. We list below the information that we require from all applicants. The following information is required to process requests for additional categories of medical devices for transitional pass-through payments.

3. Use of Information Technology

In an effort to improve information technology, we made the application process more efficient, by implementing the MEARIS™ for the CMS-10052 form. The electronic application intake system, Medicare Electronic Application Request Information System (MEARIS™), was available for the Additional Device Categories for Transitional Pass-Through Payment Status Under the Hospital Outpatient Prospective Payment System application submissions on December 2, 2021. Users can access the system, register, and complete the online application at https://mearis.cms.gov. Application submission through MEARIS™ will not only help CMS track applications and streamline the review process, but it will also create efficiencies for applicants when compared to the paper submission process. Our current estimate based on our experience remains at 10 applications per year.

4. Duplication of Efforts

Some of the information contained in this collection is similar to that submitted by applicants who apply for HCPCS codes for new items as well as some that apply for the Inpatient Prospective Payment System (IPPS) new technology payment. Our review process entails

assigning HCPCS codes to new items. Therefore, the information serves a two-fold purpose and minimizes rather than duplicates information. Additionally, there are more differences in the information collected in the IPPS and OPPS new tech applications, than similarities. Also, the collected information for both applications are collected at different periods of time, affording the opportunity for updated information to be collected during the separate application processes.

Finally, it could be said that some of the information submitted in this application is also submitted to FDA (description of device, clinical trials, price info, etc.). However, again, we believe that there is no duplication of effort as the applicant simply submits their FDA approval letter. We are also not aware of any interfacing technology that would allow seamless sharing of information regarding the description of the device, safety and effectiveness in a timely fashion, with little to no burden on staff.

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 that:

- requires respondents to report information to the agency more often than quarterly;
- requires respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- requires respondents to submit more than an original and two copies of any document;
- requires respondents to retain records, other than health, medical, government contract,

grant-in-aid, or tax records for more than three years;
- is in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- includes a pledge of confidentiality that is not supported by authority established in statue or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- requires respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.
- requires applicants to submit proprietary/confidential information in the application.

However, there are times an applicant will submit proprietary/confidential information in order to demonstrate they meet the eligibility and substantial clinical improvement criteria. In this instance, we allow applicants to classify information in the application as confidential consistent with current law. Per the application, we provide the following note: Data provided in this application or in the tracking form may become subject to disclosure. If you are providing data or information that is proprietary or otherwise protected from disclosure under the Trade Secrets Act or Exemption 4 under the Freedom of Information Act, please mark this information as such. CMS will attempt, to the extent allowed by Federal law, to keep this information protected from public view.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published in the Federal Register on TBD (87 FR 25488). No comments were received during the comment period.

The 60-day Federal Register notice published in the Federal Register on TBD (87 FR 25488).

9. Payments/Gifts to Respondents

There are no payment or gifts to respondents besides the additional payment that respondents' products could receive through the Medicare claims process if their application meets all required criterion and is subsequently approved.

10. Confidentiality

Per the answer to number '7. Special Circumstances' above, we have a note on the application that states the following:

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 unless properly noted. If you are providing data or information that is proprietary or otherwise protected from disclosure under the Trade Secrets Act or Exemption 4 under the Freedom of Information Act, please mark this information as such. CMS will attempt, to the extent allowed by Federal law, to keep this information protected from public view.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates (Hours & Wages)

Based on our recent experience, we estimate receiving approximately 7 to 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, family and general practitioner, and obstetricians and gynecologists etc.). Based on this we are using the provided occupational employment and wage estimates in the United States, to calculate an average of salary of $85/hour to calculate the cost.

$85/hr x 16 hours (average estimated time) x 10 (estimated number of applicants) = $13,600 total cost

13. Capital Costs

Capital costs are not applicable to this collection.

14. Cost to 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.

$60.94/hr (average salary GS 13/14/15) X 50 hours/ request X 10 requests = $30,470
Hourly rate per the 2022 general schedule:
GS 13: $51.18
GS 14: $60.49

GS 15: $71.15
(The average salary was calculated using the locale adjusted general schedule hourly wages for Washington-Baltimore-Arlington, DC-MD-VA-WV-PA.)

15. Changes to Burden

There are no changes to burden. Our estimate of 10 applications per year remains the same. Since the implementation of the hospital OPPS in August 2000, the number of applications received have varied, and usually dependent on the number of new devices approved by the FDA per year. The number of pass-through applications will vary from year to year and form 83-C will be filed to account for the changes, but our estimate of 10 applications remains the same. The implementation of MEARIS™ does not have an effect on burden.

CMS will add two (2) questions to the Device pass-through application on MEARIS™. The additional questions will provide more precise eligibility information to CMS earlier in the application. Applicants currently provide this information to CMS via the FDA Marketing Authorization letter attached to their application. CMS will add questions consistent with the following:

1. Provide the FDA Marketing Authorization indication and date for the technology for which the applicant is submitting a Device pass-through application.
2. If you have Breakthrough Device Designation, provide the indication and date for the technology for which the applicant is submitting a Device pass-through application?

Adding the two (2) questions in MEARIS™ does not have an effect on burden.

16. Publication/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 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 rate setting 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

The expiration date will be displayed on the bottom of the last page of the application form.

18. Certification Statement

There are no exceptions to the certification statement.