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.

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 198 new device category applications, through December 1, 2018. 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, 119 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 (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.

We are requesting reinstatement approval with change from OMB for previously approved CMS 10052.

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. Following is the information required to process requests for additional categories of medical devices for transitional pass-through payments. This information is also located on the attached application form:

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.

Describe each nominated device fully:

1. 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.
2. What does it do?
3. How is it used?
4. What makes it different from similar devices of the same type?
5. 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?
6. Submit relevant booklets, pamphlets, brochures, product catalogues, price lists, and/or package inserts that further describe and illuminate the nature of the nominated

device.

7. 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.

8. 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.

9. 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 evidence supporting the proposition that the device for which an additional category is requested meets the substantial clinical improvement criterion. 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 above in this announcement. While we prefer published peer-reviewed clinical trials, we will consider all supporting evidence.

For each claim of substantial clinical improvement over existing technologies, in table format (see Table 1 below), list the claim of substantial clinical improvement and summarize the supporting information to include relevant clinical trial(s) or data. See sample table below. (Application is incomplete without this table). Contact DevicePTapplications@cms.hhs.gov with questions concerning the table.

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. Summary of Safety and Effectiveness
3. If the device has an investigational device exemption (IDE), submit the FDA approval letter and indicate whether it is a "Category B" IDE.
4. 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.
5. 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.
6. Date of FDA approval or clearance. If necessary, submit the date of U.S. marketavailability and documentation verifying delay between FDA approval and market availability.

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.

J. Other information as CMS may require in order to evaluate specific requests or that the applicant believes CMS may need to evaluate the application.

3. Use of Information Technology

Our application instructions include a requirement to send the entire application electronically, including all attachments and appendices, via email to DevicePTapplications@cms.hhs.gov. Email versions of the application must be compatible with standard CMS software. The electronic submission of the application does not substitute for the hard copies required, although we decreased the number of hard copies from 6 to 5 copies at the time we included the electronic copy of the application. We believe the hard copies remain a necessity to ensure that delivery occurs by the mandated due date, regardless of any potential technological deficiencies.

This collection of information does not currently involve any other use of automated, electronic or other technological collection techniques. 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. Additionally, because a signature on the application is not required, the acceptability of an electronic signature is not an issue.

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 per year. However, our experience has shown a much lower number of applications. Our current estimate based on our experience is less than 10 applications per year. Also, we do not believe that the additional expense incurred to digitize the application would be cost efficient. We therefore believe that electronic submission of information is not feasible at this time.

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 would require an information collection to be conducted in a manner that requires respondents to:
- requiring respondents to report information to the agency more often than quarterly;
- requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- requiring respondents to submit more than an original and two copies of any document;
- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;

- 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;
- that 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
- requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect die information's confidentiality to the extent permitted by law.
- require 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 to the Federal Register (84 FR 8872) on 3/12/2019.

No comments were received

The 30-day Federal Register notice published to the Federal Register (FR) on TBD.

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)= $13,600total 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.

$55.39/hr (average salary GS 13/14/15) X 50 hours/ request X 10 requests = $27,693
Hourly rate per the 2019 general schedule:
GS 13: $46.66
GS 14: $54.91
GS 15: $64.59
(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

This package includes two changes that add/revise clarifying language, which are non-substantive changes intended to decrease the previously approved burden estimates. The changes include the insertion of a table in the appendix of the application intended to help applicants elucidate their significant clinical improvement claims and reviewers to have a clear tool to follow and evaluate significant clinical improvement claims.

We are adjusting the financial estimate of the burden to the Federal government and the respondents due to wage inflation over time. However, we are not adjusting the number of hours of the 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 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

The expiration date will be displayed on this document.

18. Certification Statement

There are no exceptions to the certification statement.