Supporting Statement for Paperwork Reduction Act
Information Collection for the process and information required for Transitional Pass through payments related to Drugs, Biologicals, and Radiopharmaceuticals to determine eligibility under the Outpatient Prospective Payment System and Supporting Regulations in 42 CFR Part 419, Section 419.64
(Refer to the following: http://www.cms.gov/HospitalOutpatientPPS/Downloads/drugapplication.pdf)
CMS-10008, OMB 0938-0802

A. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biological agents. As originally enacted by the Balanced Budget Refinement Act (BBRA), this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act (Pub. L. 107-186); current drugs and biological agents and brachytherapy used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. For those drugs and biological agents referred to as "current," the transitional pass-through payment began on the first date the hospital OPPS was implemented (before enactment of Benefits Improvement and Protections Act (BIPA) (Pub. L. 106-554), on December 21, 2000).

Transitional pass-through payments are also required for certain "new" drugs, devices and biological agents that were not being paid for as a hospital outpatient department (OPD) service as of December 31, 1996, and whose cost is "not insignificant" in relation to the outpatient perspective payment system (OPPS) payment for the procedures or services associated with the new drug, device, or biological. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years.

The process to apply for transitional pass-through payment for eligible drugs, biologicals, and radiopharmaceuticals can be found on the CMS website: http://www.cms.gov/HospitalOutpatientPPS/Downloads/drugapplication.pdf. We have qualified thousands for transitional pass-through payments through our application process. However, 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 and pharmaceutical companies that bring to our attention specific new drugs, biologicals and radiopharmaceuticals to be evaluated for transitional pass-through status.

B. Justification

1. Need and Legal Basis

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)(i) provides that the additional payment for drugs and biologicals be the amount by which the amount determined under section 1842(o) of the Act exceeds the portion of the otherwise applicable hospital outpatient department fee schedule amount that the Secretary determines to be associated with the drug or biological.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs and biologicals (assuming that no pro rata reduction in pass-through payment is necessary) as the amount determined under section 1842(o) of the Act. Section 303(c) of Pub. L. 108-173 amended Title XVIII of the Act by adding new section 1847A. This new section establishes the use of the average sales price (ASP) methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. Therefore, as we stated in the November 15, 2004 Federal Register (69 FR 65776), in CY 2005, we will pay under the OPPS for drugs, biologicals and radiopharmaceuticals with pass-through status consistent with the provisions of section 1842(o) of the Act as amended by Pub. L. 108-173 at a rate that is equivalent to the payment these drugs and biologicals will receive in the physician office setting, and established in accordance with the methodology described in the CY 2005 Physician Fee Schedule final rule. Information on Average Sales Price is found at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/. The intent of these provisions is to ensure that timely beneficiary access to new pharmacological technologies is not jeopardized by inadequate payment levels.

2. Information Users

The process and information required to determine the eligibility of drugs, biologicals and radiopharmaceuticals for transitional pass-through payment status is posted on the CMS web site, specifically at: http://www.cms.gov/HospitalOutpatientPPS/Downloads/drugapplication.pdf.

Interested parties such as hospitals, pharmaceutical companies, and physicians will apply for transitional pass-through payment for drugs, biologicals, and radiopharmaceuticals used with services covered under the hospital OPPS. After we receive all requested information, we will evaluate the information to determine if the criteria for making a transitional pass-through payment are met and if an interim healthcare common procedure coding system (HCPCS) code for a new drug, biological, or radiopharmaceutical is necessary. We will advise the applicant of our decision, and update the hospital OPPS during its next scheduled quarterly update to reflect any newly approved drug, biological, or radiopharmaceutical. We list below the information that we will require from all applicants. Most of the information requested is similar to that posted previously on our web site and discussed in the April 7, 2000 final rule. Based on experience gained in processing transitional pass-through and new

technology applications, we have reworded some of the statements for clarity and have more clearly requested information in a format that will allow us to determine if the drug, biological, or radiopharmaceutical meets the cost significance test, as well as to estimate the associated pass-through payment amount. In addition, we have also eliminated the requirement for applicants to obtain a national Level II HCPCS code prior to seeking transitional pass-through payment eligibility, or provide us with a copy of their application for a national HCPCS code, as we had originally required in the April 7, 2000 final rule. Below is the information required to process requests for drug, biological and radiopharmaceutical transitional pass-through payments.

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 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 drugs, biologicals, and radiopharmaceuticals 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 remains at 30 applications per year. We, therefore, believe that electronic submission and/or electronic storage 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 national HCPCS codes for new items. Therefore, the information required of applicants 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 drug or biological manufacturers that wish to have items evaluated for transitional pass-through payment status under the hospital OPPS. 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 pass-through payment for new drugs, biologicals, and radiopharmaceuticals. 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 drugs or non-implantable biologicals 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

The 60-day Federal Register notice published on July 17, 2018 (83 FR 33223). The 30-day Federal Register notice published on October 4, 2018 (83 FR 50100).

9. Payments/Gifts To Respondents

There is no payment or gift to respondents.

10. Confidentiality

Because CMS intends to make information used in the rate-setting 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)

We anticipate receiving a total of 30 drugs, biological and radiopharmaceutical requests annually for transitional pass-through payment determination. We estimate that it will take approximately 16 hours on average for an applicant (healthcare practitioners and technical occupations) to compile the information requested. Based on an assumption of 30 requests, the total burden is 16 hours (average time) x 30 = 480 hours (annual).

As referenced earlier, we believe healthcare practitioners and technical occupations will be responding to the information collection requirements. Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2017) for Category 29-0000 (Healthcare Practitioners and Technical Occupations), which can be found at http://www.bls.gov/oes/current/oes_md.htm, the mean hourly wage for a healthcare and technical occupations is $41.79. We have added 100% of the mean hourly wage to account for fringe and overhead benefits, which calculates to $83.58 ($41.79 +$41.79). We estimate the total annual cost to be $40,118.40 (480 hours x $83.58/hour).

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, and database inputs. We estimate the total time to process, evaluate and reach a decision is 40 to 60 hours per drug, biological, or radiopharmaceutical application. We use the midpoint of this range to derive the following estimate.

$60/hr (average salary GS 13/14/15) x 50 hours/ request x 30 requests = $90,000

15. Changes to Burden

There are no changes to burden. Our estimate of 30 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 drugs approved by the FDA per year. Many of the drugs, biologicals, and radiopharmaceuticals that were approved for pass-through status two years ago have already met the 2 to 3 year period for pass-through payment. As a result, we receive only pass-through applications for new drugs, biologicals, and radiopharmaceuticals. The number of pass-through applications will vary from year to year and form 83-C will be filled to account for the changes, but our estimate of 30 applications remains the same.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs, biologicals and radiopharmaceuticals (assuming that no pro rata reduction in pass-through payment is necessary) as the amount determined under section 1842(o) of the Act. Section 303(c) of Pub. L. 108-173 amended Title XVIII of the Act by adding new section 1847A. This new section establishes the use of the average sales price (ASP) methodology for payment for drugs and non-implantable biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. Therefore, as we stated in the November 15, 2004 Federal Register (69 FR 65776), in CY 2005, we will pay under the OPPS for drugs, biologicals and radiopharmaceuticals with pass-through status consistent with the provisions

of section 1842(o) of the Act as amended by Pub. L. 108-173 at a rate that is equivalent to the payment these drugs, biologicals and radiopharmaceuticals will receive in the physician office setting, and established in accordance with the methodology described in the CY 2017 Physician Fee Schedule final rule. Information on Average Sales Price is found at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/.

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 drug, biological or radiopharmaceutical 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 Federal Register notice and distributed via program transmittals 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 drugs, biologicals and radiopharmaceuticals.

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.

C. Collections of Information Employing Statistical Methods

Not applicable to this collection.