Supporting Statement for Paperwork Reduction Act
Information Collection for Transitional Pass-through Payments
Related to Drugs and Biologicals Under the Outpatient Prospective Payment System and
Supporting Regulations in 42 CFR Part 419, Section 419.64
(Refer to the following: http://www.cms.hhs.gov/providers/hopps and Federal Register rule of April 7, 2000)

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 As originally enacted by the BBRA, this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the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 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 OPD service as of December 31, 1996, and whose cost is "not insignificant" in relation to the 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 and biological agents can be found on pages of our CMS website: http://www.cms.hhs.gov/providers/hopps. We have qualified more than 1700 items 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 or biologicals 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 and biologicals 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 and biologicals for transitional pass-through payment status is posted on the CMS web site, specifically at: http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage.

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 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 and biological transitional pass-through payments:

1. The trade name and generic name of the product.
2. A detailed description of the clinical application of the product:
    a. What it is and what it does.
    b. The form in which it is supplied (i.e., solution, tablet, etc.).
    c. Method of administration (intramuscularly, intravenously, orally, subcutaneously, sublingually, etc.).
    d. Manner of packaging (indicate dosages/concentrations per ml, per tablet, per mCi, etc.).
    e. The usual minimum dosage per day for one patient.
    f. The usual maximum dosage per day for one patient.
    g. The Healthcare Common Procedure Coding System (HCPCS) code(s), if any, used to identify the product. Specifically, which code(s) is/are used to report the use of this drug or biologic to third party payers? (NOTE: APPROVAL OF A DRUG OR BIOLOGICAL FOR A TRANSITIONAL PASS-THROUGH PAYMENT UNDER THE OPPS IS NOT CONTINGENT ON PRIOR ASSIGNMENT OF A NATIONAL HCPCS CODE.)
3. A copy of the most recently published average wholesale price (AWP), including the date of publication and compendium where published.
4. Average Sales Price (ASP), or Wholesale Acquisition Cost (WAC).
5. The current cost of the drug, biological, or radiopharmaceutical to hospitals, that is, the actual cost paid by hospitals 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 actual cost to hospitals for a specific drug, biological, or radiopharmaceutical specified in terms of dosage and concentration.
6. The date of sale of first unit.
7. Usage (percent and volume) by site of service (i.e., inpatient, outpatient, physician office, etc.). List projected volume separately by the following categories: Medicare Inpatient Hospital; Medicare Outpatient Hospital; Medicare Physician's Office; Medicare Ambulatory Surgical Center; and other sites of services. Projected volume should reflect one full year of utilization.
8. Using HCPCS Level I and/or Level II code(s); list all of the specific procedure(s) and/or services with which the nominated drug, biological, or radiopharmaceutical is used, including the percentage of utilization projected to be associated with each HCPCS code. If the drug, biological, or radiopharmaceutical replaces an existing product, identify the trade/brand name of the existing product and any HCPCS code(s) used to identify the existing product.
9. A copy of the Food and Drug Administration (FDA) approval/clearance letter for the product.
10. A copy of the package insert.
11. For biological application(s), a copy of the United States Pharmacopeia (USP) Monograph for the product.
12. Applicant name(s), company name, 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 applicant name, company 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.

13. Other information as CMS may require to evaluate a specific request or that the applicant believes CMS may need to evaluate the application.

IN ADDITION, answer 13A. or 13B., whichever is applicable.

13A. For drugs and biologicals OTHER THAN contrast agents or radiopharmaceutical products, specify how dosages are measured, i.e., in milligrams, micrograms, etc.

13B. For radiopharmaceutical drugs and biological products and for contrast agents, specify the following information:

a. Indicate whether the product is available in milligrams (mg), millicuries (mCi), or microcuries (uCi), including concentration before and after reconstitution.
b. If the AWP is stated “per vial” or "per ampule," indicate how many doses can be administered from one vial or one ampule.
c. If the AWP is stated “per dose,” "per vial," or "per ampule," but the item is administered in milligrams (mg), millicuries (mCi), or microcuries (uCi), indicate how many mg, mCi, or uCi are in one dose, one vial and/or one ampule.

- Note that a separate application is required for each distinct drug, biological, or radiopharmaceutical included in a request. For example, if an applicant requests transitional pass-through status for five new drugs, the required information listed above must be completed for each of the five drugs.

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 is 10 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 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 was published on November 29, 2007.

The April 7, 2000 Federal Register final rule that sets forth the criteria we use to establish transitional pass-through payment for drugs and biologicals can be viewed from this CMS website: http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/list.asp?listpage=3. Also, the April 6, 2004, Average Sales Price (ASP) Data Submission Interim Final Rule informs the manufacturers to provide Average Sales Price data for Medicare Part B drugs.
We have 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, PHARMA, and hospitals regarding implementation of the transitional pass-through provisions. Based on these discussions and our knowledge of the requirements for FDA approval/clearance to market many of the items that will be submitted to us for review and the requirements for HCPCS codes for such items, we believe that the information we seek to collect is readily available to the applicants.

9. Payments/Gifts To Respondents

There is no payment or gift to respondents.

10. Confidentiality

Because CMS intends to make 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)

We anticipate receiving approximately 6 drug and biological and 4 radiopharmaceutical requests annually for transitional pass-through payment determination. We estimate that it will take approximately 16 hours on average for an applicant to compile the information requested. Based on an assumption of 10 requests, the total burden is 16 hours (average time) X 10 = 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, 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.

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

15. Program Changes

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 and biologicals 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 43 hour decrease in burden from the last filing is due to an estimated decrease in respondents from 58 to 10 annually. Since the implementation of the hospital OPPS in August 2000, the number of applications has decreased. Many of the drugs, biologicals, and radiopharmaceuticals that were approved for pass-through status at the beginning of OPPS have already met the 2 to 3 year period for pass-through payment. As a result, we now receive only pass-through applications for new drugs, biologicals, and radiopharmaceuticals. The number of requests will vary from year to year, but 83-C forms will be filed to account for the changes.

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 or biological 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 memorandum 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 and biologicals.

17. Expiration Date

This collection does not lend itself to the displaying 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 special payment mechanism of transitional pass-though payments for drugs and biologicals 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.