Supporting Statement for Paperwork Reduction Act
Information Collection for New Technology Payments for APCs
Under the Outpatient Prospective Payment System
(Refer to the following: http://www.cms.gov/ web notice)

A. Background

In the April 7, 2000 final rule first implementing the hospital outpatient prospective payment system (OPPS), we created a set of New Technology ambulatory payment classifications (APCs) to pay for certain new technology services under the OPPS. These APCs are intended to pay for new technology services that were not covered by the transitional pass-through payments provisions authorized by the Balanced Budget Refinement Act (BBRA) of 1999. (Since implementation of the hospital outpatient prospective payment system (OPPS) on 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.)

We indicated that the New Technology APCs would be defined on the basis of costs and not the clinical characteristics of a service. We initially established APC groups 0970 through 0984 as the New Technology APCs with costs ranging from less than $50 to $6,000. The New Technology APCs that were implemented on August 1, 2000 were populated with 11 new technology services. We stated in the April 7, 2000 rule that we will pay for an item or service under a New Technology APC for at least 2 years but no more than 3 years, consistent with the term of transitional pass-through payments. After that period of time, during the annual APC update cycle, we intend to move the item or service into the existing APC structure based on its clinical attributes and, based on claims data, its resource costs.

In the April 7, 2000 rule, we specified an application process and the information that must be supplied for us to consider a request for payment under the New Technology APCs (65 FR 18478). We also described the five criteria we would use to determine whether a service is eligible for assignment to a new technology APC group. These criteria, which we are currently using (with some modifications adopted beginning with 2002 described below), are as follows: The item or service is one that could not have been billed to the Medicare program in 1996 or, if it was available in 1996, the costs of the service could not have been adequately represented in 1996 data. The item or service does not qualify for an additional payment under the transitional pass-through payments provided for by section 1833(t)(6) of the Act. The item or service is not described by an existing Healthcare Common Procedure Coding System (HCPCS) code. The item or service falls within the scope of Medicare benefits under section 1832(a) of the Act. The item or service is determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act. In addition, we added 2 additional criteria in our November 30, 2001 final rule (66 FR 59897), effective January 1, 2002. The service must be a complete service and the service cannot be appropriately placed in a regular APC. We also modified the criterion that the service could not have been

represented by our 1996 data to beyond 1996. The revised criterion became: The service could not have been adequately represented in the claims data used for the most current annual OPPS payment update. We also clarified that New Technology APCs would be used for services only, not items such as drugs, biologicals or devices. These revisions are expanded upon below.

In addition, we described in the April 7, 2000 rule the application process that we would use to determine eligibility for assignment to a New Technology APC and the process that we would use to promptly assign interim "C" codes under the Healthcare Common Procedure Coding System (HCPCS) to bill for services, if no national codes have been assigned.

We posted the application process on our web site at **http://www.cms.gov**. Services were only considered eligible for assignment to a New Technology APC if we listed them in one of a number of lists published in Medicare Program Memoranda, which are posted to our web site. We established a quarterly application process by which interested parties could submit applications to us for particular services.

Based on the experience we gained and data we collected since publication of the April 7, 2000 final rule, we revised, as published in our November 30, 2001 final rule, the following: (a) the definition of what is appropriately paid for under the New Technology APCs; (b) the criteria for determining whether a service may be paid under the New Technology APCs; (c) the information that we would require to determine eligibility for assignment to a New Technology APC; and (d) the length of time we will pay for a service in a New Technology APC. (66 FR 59897)

In our November 30, 2001 final rule we changed some of the information that interested parties must submit to have a service or procedure considered for assignment to a New Technology APC. Based on our experience in reviewing New Technology APC applications, we believed that the additional information requested would better assist us in making a timely determination of eligibility for placement in these APCs than the information we previously requested. These changes were included in our previous PRA submissions.

Both the New Technology APC provision and the transitional pass-through provisions provide ways for ensuring appropriate payment for new technologies for which the use and costs are not adequately represented in the base year claims data on which the outpatient PPS is constructed. Although individual drugs and biologicals and categories of medical devices will receive transitional pass-through payments for 2 to 3 years from the date payment is initiated for the specific item or category, the underlying statutory provision is permanent and provides an on-going mechanism for timely reflecting the introduction of new items into the payment structure. New Technology APCs are designed to ensure appropriate payment for new technology services that are not covered by the transitional pass-through provisions.

We assign new services to the New Technology APCs that we determine cannot be placed appropriately in clinical APCs. Under our current policy, we retain services in a New Technology APC until we gain sufficient information about actual hospital costs incurred to furnish a new technology service. Effective January 1, 2002, under provisions of our

November 30, 2001 final rule, we move a new technology service to a regular APC at such time as we gain adequate information about actual hospital costs incurred to furnish a new technology service. We reassign these services to other clinically relevant APCs with procedures using comparable resources. If we cannot move the new technology service to an existing clinical APC because it is dissimilar clinically and with respect to resource costs from procedures assigned to all other APCs, we create a separate clinical APC for such service.

As indicated in the previous PRA submissions for OPPS information collections, we are submitting separate PRA clearance packages for each of the three payment mechanisms that require an application process for an item or service under the OPPS. Therefore, we will describe the application process for pass-through payment for drugs and biologicals and for new device categories in different PRA submissions. This document discusses the process for assignment of services to New Technology APCs.

We renumbered and expanded the new technology APCs for 2004 (November 7, 2003 final rule; 68 FR 63485-6), from APC 1501 through 1574, with costs ranging from below $50 to $10,000. We received 25 applications for assignment to New Technology APCs in 2002 and 2003, 7 of which we determined were eligible for assignment to New Technology APCs. The current series of New Technology APCs for 2010 (November 20, 2009 final rule; 74 FR 60688-89) consist of APCs 1491 through 1574, with costs ranging from below $10 to $10,000. We received 10 applications for assignment to New Technology APCs in 2008 and 2009, none of which we determined were eligible for assignment to New Technology APCs.

B. Justification

1. Need and Legal Basis

CMS needs to keep pace with emerging new technologies and make them accessible to Medicare beneficiaries in a timely manner. It is necessary that we continue to collect appropriate information from interested parties such as hospitals, medical device manufacturers, pharmaceutical companies and others that bring to our attention specific services that they wish us to evaluate for New Technology APC payment.

We are making no changes to the information that we collect. The information that we seek to continue to collect is necessary to determine whether certain new services are eligible for payment in New Technology APCs, to determine appropriate coding and to set an appropriate payment rate for the new technology service. The intent of these provisions is to ensure timely beneficiary access to new and appropriate technologies.

2. Information Users

Interested parties such as hospitals, device manufacturers, pharmaceutical companies, and physicians use this information to apply for New Technology APC payments for certain services covered in the OPPS. After we receive all requested information, we evaluate the information to determine if a service is eligible for placement into a New Technology APC. We advise the applicant of our decision, and update the OPPS during its next scheduled quarterly update to the OPPS to reflect the newly approved services. We list below the

information that we request from all applicants. If a new service has not yet been assigned a national HCPCS code, we will identify the service with an interim HCPCS code that will be used for billing under the OPPS. Following is the information required to process applications for services requested for placement into New Technology APCs:

1. The name by which the service is most commonly known.
2. A clinical vignette, including patient diagnoses that the service is intended to treat, the typical patient, and a description of what resources are used to furnish the service by both the facility and the physician. For example, for a surgical procedure this would include staff, operating room, and recovery room services as well as equipment, supplies, and devices, etc.
3. A list of any drugs or devices used as part of the service that require approval from the Food and Drug Administration (FDA) and information to document receipt of FDA approval/clearances and the date obtained, including a copy of the FDA approval or clearance letter.
4. A description of where the service is currently being performed (by location) and the approximate number of patients receiving the service in each location.
5. An estimate of the number of physicians who are furnishing the service nationally and the specialties they represent.
6. Information about the clinical use and efficacy of the service such as peer-reviewed articles.
7. The CPT or HCPCS Level II code(s) that are currently being used to report the service and an explanation of why use of these HCPCS codes is inadequate to report the service under the OPPS.
8. A list of the CPT or HCPCS Level II codes for all items and procedures that are an integral part of the service. This list should include codes for all procedures and services that, if coded in addition to the code for the service under consideration for New Technology APC status, would represent unbundling.
9. A list of all CPT and HCPCS Level II codes that would typically be reported in addition to the service.
10. A proposal for a new HCPCS code, including a descriptor and rationale for why the descriptor is appropriate. The proposal should include the reason why the service does not have a CPT or HCPCS Level II code, and why the CPT or HCPCS Level II code or codes currently used to describe the service are inadequate.
11. An itemized list of the costs incurred by a hospital to furnish the new technology service, including labor, equipment, supplies, overhead, etc.
12. 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.
13. Other information as CMS may require to evaluate specific requests or that the applicant believes CMS may need to evaluate the application.

We inform applicants that CMS may request other information in order to evaluate specific requests. However, the burden is on us to establish the need for additional information.

3. Use of 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 a detailed description of the clinical application and a clinical vignette 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.
Because a signature on the application is not required, the acceptability of an electronic signature is not an issue.

4. Duplication of Efforts

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 businesses such as providers of hospital outpatient services and small device, drug or biological agent manufacturers that wish to have services evaluated for New Technology APC payment under the 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 the information is also readily available to hospitals through their record keeping systems.

6. Less Frequent Collection

This information is collected as determined by interested parties for possible additional payment for new services. This is not a regularly scheduled information collection. Interested parties determine individually the frequency and timing of information collection based on the number of services 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

for assignment of new services to New Technology APCs, nor would we be able to place new services into New Technology APCs.

7. Special Circumstances

Because the nature of the applications is often complex, we have a team of CMS clinical staff who review the applications. This necessitates circulating more copies of each application than an original and two copies. We request that six copies (i.e., original plus five copies) of each application be submitted.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice (Vol. 75, No. 204, pg 65350) was published on October 22, 2010, and no comments were received.

We had numerous meetings and discussions with individual device drug and biological manufacturers, the Advanced Medical Device Manufacturers Association, Medical Manufacturers Device Association, Nuclear Medicine APC Task Force, PHARMA, and hospitals in response to implementing the transitional pass-through and New Technology APC provisions. We also have frequent meetings and discussions with individual device manufacturers and their associations concerning applications and our process. Based on these discussions and our experience over the past several years, and our knowledge of the requirements for FDA approval/clearance to market many of the items used in the performance of new services 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 15 applications per year for new services to be assigned to New Technology APCs annually for eligibility determination, based upon our experience over recent years.

We estimate that it will take approximately 12 hours on average for an applicant to compile the information requested, with the actual time being dependent on the complexity of the application being submitted. Based on an assumption of 15 requests the total annual burden is 12 hours x 15 = 180 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 12 hours (average estimated time) x 15 (estimated number of applicants) = $9,000 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 a review committee of 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 New Technology APC application. We use the midpoint of this range to derive the following estimate.

$50/hr (average salary GS 13/14/15) X 50 hours/ request X 15 requests = $37,500

15. Program Changes

There are no program changes at this time.

16. Publication and Tabulation Dates

We do not plan to publish the information collected under this submission. The information will be used to determine eligibility for the special the New Technology APC payment provision included in the April 7, 2000 and November 30, 2001 final rules. If services are

determined to be eligible they will be included on a list of identified pass-through/ new technology items and services, which will be posted on our web site, published in the appropriate *Federal Register* notice and/or 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 payments for new services such as that submitted in the applications for assignment to New Technology APCs.

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis. To include an expiration date would result in having to discard a potentially large number of forms.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

Not applicable to this collection.