Supporting Statement for Paperwork Reduction Act
Information Collection for New Technology Payments for APCs
Under the Outpatient Prospective Payment System
(Refer to the following: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/downloads/newtechapc.pdf) CMS-10054, OMB: 0938-0860

Background

This is a request for a reinstatement of approval for the information collection request previously approved under OMB control number 0938-0860. The approval lapsed due to administrative issues.

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. 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 clinical 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. In the November 30, 2001 final rule 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 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/CMS-Program-Memoranda.html). 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. There have been no changes in the information requirements since the November 30, 2001 final rule.

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 reflecting the introduction of new items into the payment structure in a timely manner. New Technology APCs are designed to allow 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 (OMB Control Number 0938-0802) and for new device categories (OMB Control Number 0938-0857) in different PRA submissions. This document discusses the process for assignment of services to New Technology APCs.

The current series of New Technology APCs for 2017 (November 14, 2016 final rule; the list of all clinical and New Technology APCs are now found on the web, at https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-ServicePayment/HospitalOutpatientPPS/Downloads/CMS-1656-FC-2017-OPPS-FR-Addenda.zip) consist of APCs 1491 through 1599 and APCs 1901 through 1906, with costs ranging from below $10 to $160,000. We received 22 applications for assignment to New Technology APCs from 2013 through 2016, two of which we determined were eligible for assignment to New Technology APCs.

B. Justification

1. Need and Legal Basis

Section 1833(t)(6) of the Social Security Act (the Act) states, "The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services)." In accordance with the Act, 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

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.* This information allows the evaluation team to identify the medical service described in the New Technology application. It also is information that may be used to create a procedure code description if the medical service is assigned a temporary procedure code.
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.* This information helps CMS to determine if the medical service described in the New Technology application is a new service that is not described by an existing CPT or HCPCS procedure code. Furthermore, this information helps CMS determine if there is a clinical APC that the medical service may be assigned. If there is no appropriate existing APC

available for the medical service, it will be assigned to a New Technology APC. The clinical vignette also helps the evaluation team estimate the cost of the medical service.

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. NOTE: Applicants are advised not to apply for a New Technology APC assignment until any required FDA approvals or clearances are received. An application is not complete without the required FDA information.*

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.* This information helps CMS gain a better understanding about the cost of the medical service and the resources required for the service.

5. *An estimate of the number of physicians who are furnishing the service nationally and the specialties they represent.* This information helps CMS to determine the anticipated volume of services and provides additional information on the resources expected to be used to perform the service.

6. *Information about the clinical use and efficacy of the service, such as peer reviewed articles.* This information complements the information provided in the clinical vignette and helps CMS learn more about the medical service and the resources used for the services.

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.* This information give the applicant the opportunity to demonstrate why a new procedure code and description need to be established for the medical service. Many medical services that are included in New Technology applications are billed with an unlisted CPT code.

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 status, would represent unbundling.* This information complements the clinical vignette and helps CMS understand the procedures that are a part of the medical service to ensure that the technology represents a complete medical service that is not already described by existing procedure codes.

9. *A list of all CPT and HCPCS Level II codes that would typically be reported in addition to the service.* This information gives CMS additional information about

the medical service and provides guidance on whether the procedure should be assigned to a clinical or New Technology APC.

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.* This information helps CMS determine if a new procedure code needs to be established for the medical service and gives the evaluation guidance on the text to include for the descriptor of the temporary procedure code.

11. *An itemized list of the costs incurred by a hospital to furnish the new technology service, including labor, equipment, supplies, overhead, etc.* This information helps determine the appropriate clinical or New Technology APC to assign the medical service.

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.* This information gives CMS a point of contact for the New Technology application to send communications related to 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.* CMS is open to reviewing any relevant information related to the medical service described in the New Technology 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

Our application instructions include a requirement to send the entire application electronically, including all attachments and appendices, via email to NewTechAPCapplications@cms.hhs.gov. Email versions of an application must be compatible with standard CMS software, such as Adobe Acrobat Pro DC and Microsoft Word 2013.

This collection of information does not currently involve the use of automated, electronic or other technological collection techniques.

Because a signature on the application is not required, the acceptability of an electronic signature is not an issue.

4. Duplication of Efforts

This information collection does not duplicate other efforts. Each application typically contains unique information that cannot be obtained from any other source.

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

Not applicable.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published on October 18, 2017(82FR48514) and 30-day Federal notice published on January 19, 2018(83FR2784). No comments received on this package.

9. Payments/Gifts to Respondents

There are no gifts to respondents for this information collection request.

New Technology APCs are defined on the basis of costs and not the clinical characteristics of a service. 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, the resource costs for the service. However if the service has less than 100 claims, it may be assigned to a New Technology APC for longer than 3 years until enough claim volume is generated to assign the service to a clinical APC.

The New Technology application process provides a pathway for new services that cannot be classified into a clinical APC to receive payment in the OPPS to receive payment consummate with the cost of the new service. The New Technology application process also provides a pathway for new services that can be assigned to a clinical APC to receive a payment that reflects the resources expended for a procedure. Unlisted procedures may only receive the lowest level of payment in a clinical APC family with multiple resource levels, and many clinical APC have five or more resource levels. Once a new service receives a temporary procedure code, it may be assigned to any resource level within the clinical APC family, which permits the new service to be assigned to a resource level that is more representative of the costs of the new procedure.

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)

Based on our recent experience, we estimate receiving approximately 4 to 10 requests annually 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 16 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 10 requests the total annual burden is 16 hours x 10 = 160 hours.

The information for various items will be compiled by top executives. Therefore we are using a wage of $61/hour, the mean wage for top executives, to calculate the cost based on the most

recent Bureau of Labor Statistics Occupational and Employment Data (May 2016).[1] We have added 100% of the mean hourly wage to account for fringe and overhead benefits, which total to $122 ($61 + $61).

> $122/hr x 16 hours (average estimated time) x 10 (estimated number of applicants) = $19,520 total cost

The copy submission requirement is voluntary and applicants usually wait as close to the quarterly deadlines to submit their applications. We estimate three hard copies of the application will be submitted with each copy being, on average, 50 sheets of paper. We estimate the cost of the paper and printing of the applications would be $10. We also expect that most applicants would use priority mail delivery services to send the hard copy applications which would cost an additional $6.70[2].

> $10 to print 3 copies of the application + $6.70 for overnight delivery = $16.70 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.

($55/hr (average salary GS 13/14/15) + $55/hr (fringe and overhead benefits)) X 50 hours/ request X 10 requests = $55,000

15. Program Changes

There are no program changes and no changes to our burden estimates. The cost to the federal government has increased because of an increase in average salary. The total annual cost has also increased due to the addition of 100% of the mean hourly wage to account for fringe and overhead benefits in our calculations.

[1] https://www.bls.gov/oes/current/oes_nat.htm#00-0000
[2] https://www.usps.com/business/prices.htm

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, in the addenda of appropriate *Federal Register* notice, and/or distributed via program transmittals 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 payments for new services such as that submitted in the applications for assignment to New Technology APCs.

17. Expiration Date

The expiration date will be reported in the PRA statement on the first page of the document immediately after the OMB control number.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

Not applicable to this collection.