Supporting Statement Part A for Paperwork Act Submissions

PRA for Add-On Payments for New Medical Services and Technologies Paid Under the Inpatient Prospective Payment System

A. Background

For consideration for add-on payments for new medical services or technologies for FY 2019 and subsequent Federal Fiscal Years, applicants must submit a formal application (which includes a tracking form). The application includes questions regarding the three criteria that applicants must answer in order for CMS to determine if the applicant is eligible for add-on payments for new medical services or technologies for the upcoming fiscal year. Complete application information, along with final deadlines for submitting a full application, is posted on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* For the convenience of the applicants, the application is posted on the CMS website in multiple electronic formats. Applicants then submit an electronic copy and hard copy to CMS by the deadline posted on the CMS website. We estimate receiving approximately / potentially 10 to 20 applications annually. This estimated number of applications is based on the fact the number of applications we receive each year has gradually been increasing from less than 5 to 9. We believe that we will continue to receive an increased number of New Technology Add-On Payment applications.

Update

As discussed in section 12 of this document, we have updated the estimated annual number of respondents from 15 to 32. We are submitting this updated estimate to OMB for review and approval as part of a non-substantive change request.

B. Justification

1. Need and Legal Basis

Sections 1886(d) (5) (K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ‘‘new technologies’’) under the IPPS. Section1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, ‘‘based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.’’

The regulations at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined

to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies.

We use the application in order to determine if a technology meets the new technology criteria.

2. Information Users

The application(s) will be evaluated by the Division of Acute Care (DAC) New Technology Team and two to three Medical Officers in the Hospital and Ambulatory Policy Group (HAPG). This team will review each application against the new technology add-on payment criteria and provide recommendations to CMS and HHS leadership for decision. Per the statute, determinations and eligibility for add-on payments for new medical services or technologies must go through rulemaking giving the opportunity for the public to comment.

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies under the IPPS. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that the process must apply to a new medical service or technology if, "based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate." Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered "new" if it meets criteria established by the Secretary after notice and opportunity for public comment.

Section 412.87(b)(3) provides that, to receive special payment treatment, new technologies meeting this clinical definition must be demonstrated to be inadequately paid otherwise under the DRG system. For applicants for new technology add-on payments for FY 2005 and forward, we established the criteria that will be applied to assess whether technologies would be inadequately paid under the DRGs the lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges (based on the national case weighted cost-to-charge ratio) or 75 percent of 1 standard deviation (based on the logarithmic values of the charges and transformed back to charges) beyond the geometric mean standardized charge for all cases in the DRGs to which the new technology is assigned (or the case weighted average of all relevant DRGs, if the new technology occurs in many different DRGs).

In order to qualify for the new technology add-on payments, a specific technology must be "new" under the requirements of §412.87(b)(2) of our regulations. The statutory provision contemplated the special payment treatment for new technologies until such time as data are available to reflect the cost of the technology in the DRG weights through recalibration (no less than 2 years and no more than 3 years).

Responses to the questions in the form helps CMS determine if and how the applicant meets the established criteria. Responses also helps CMS calculate payments for approved technologies.

Responses to questions 1 through 4 provide general information about the new technology. These responses are used to create a tracking a form which is published annually to allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule.

Responses to question 5 through 17 provide information needed to determine “newness” of the technology. To qualify for a new technology add-on payment, the technology or service must not

be reflected in the data used to establish the Medicare-Severity Diagnosis Related Groups (MS-DRGs).
Responses to questions 18 through 26 provide data to support the cost criterion. To meet the cost criterion, the technology or service must result in average charges for cases using the technology in excess of the cost thresholds set out in a published table, Table 10 – Final New Technology Payment Thresholds, of the annual IPPS final rule.
Responses to questions 27 and 28 describe how the technology meets the clinical improvement criterion. The applicant may provide the results of clinical trials, published studies and peer-reviewed articles to support their claims of substantial clinical improvements.

3. Use of Information Technology

Applications are available for download from the CMS website. Once downloaded, applicants are required to submit an electronic copy and may choose to voluntarily provide a hardcopy of the tracking form, application and any supplemental clinical or cost data they wish to submit.

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 may affect small entities such as small device manufacturers that wish to apply for the New Technology Add-On Payment. To minimize the burden, we have limited the specific information being collected solely to the essential elements necessary to make the appropriate decisions against the New Technology Add-On Payment Criteria noted.

6. Less Frequent Collection

This information is collected upon request by the applicant in order to comply with current regulatory requirements. Reducing or eliminating this collection would contradict the current regulation.

7. Special Circumstances

Per our application we request that the applicant submit an e-copy of their tracking form, application, and any supporting documentation they wish to include. The applicant may voluntarily submit a hardcopy if desired.

We do not require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;

We do not 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 criteria for new technology add on payments. 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 notice was published on January 17, 2017(82FR4887) and the 30-day Federal Register published on June 2, 2017(82FR28065) with no comments received.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

If approved, new technology add-on payment policy provides additional payments for cases with high costs involving eligible new technologies while preserving some of the incentives under the average-based payment system. The payment mechanism is based on the cost to hospitals for the new technology. Under §412.88, Medicare pays a marginal cost factor of 50 percent for the costs of the new technology in excess of the full DRG payment. If the actual costs of a new technology case exceed the DRG payment by more than the estimated costs of the new technology, Medicare payment is limited to the DRG payment plus 50 percent of the estimated costs of the new technology.

10. Confidentiality

Per the answer to number ‘7. Special Circumstances’ above, we have a note on the application that states 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.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

Based on our recent experience, in the next several years we estimate receiving approximately / potentially 10 to 20 applications annually for the New Technology Add-On Payment Policy. We have chosen the average of 15 applications per year for purposes of this PRA. This estimated number of applications is based on the fact the number of applications we receive each year has gradually been increasing from less than 5 to 9. We believe that we will continue to receive an increased number of New Technology Add-On Payment applications and our estimate of the number of applications (10-20) is realistic and using the average of 15 applications for the purposes of this PRA is reasonable.

We are increasing the number of respondents under this collection from 15 to 32 and the burden will be adjusted accordingly. The increased number of respondents is necessary to accommodate the upward trending number of applications that have been received since the approval of this collection. The number of New Technology Add-On Payment applications received since the approval of this collection increased from 9 to 18 and this volume of applicants was greater than anticipated. We have also noticed the volume continuing to increase. Therefore, we have adjusted the estimate of the number of applicants and revised the burden accordingly. None of the other components of the currently approved information collection have changed. Based on our recent experience, in the next several years we estimate receiving approximately 27 to 36 applications annually for the New Technology Add-On Payment Policy. We have chosen the average of 32 applications per year for purposes of our revised estimate in this PRA. This estimated number of applications is based on the fact that in the one year since the approval of this collection, the number of applications we received increased from 9 to 18. We believe that we will continue to receive an increased number of New Technology Add-On Payment applications and our estimate of the number of applications (27 to 36) is realistic if the volume of the current upward trend remains consistent. We also believe that using the average of 32 applications for the purposes of this PRA is reasonable.

We consider increasing the number of respondents under this collection to be nonsubstantial since it does not constitute changes to the intent or substance of the application nor does it change the burden estimate per individual applicant. All of the application documents, the applicant requirements, and the time estimates per applicant for this collection remain unchanged.

We estimate the time associated with collecting the information for the application and submitting the data electronically to CMS to be 4 working days (4 days x 8 hours per day= 32 hours). We believe this is reasonable as the information submitted by the applicant is typically information that the applicant already has with regard to their technology (cost and clinical information). Once an applicant submits an application to CMS the application is then reviewed by staff at CMS. We estimate an additional eight hours per provider for answering questions and clarifying information during the review. We estimate 1,280 total burden hours for the submission of one application (that is 32 applications x 40 hours). When computed, assuming a current salary of $59.71 per hour (based on data from the Bureau of Labor and Statistics website at http://www.bls.gov/oes/current/oes_nat.htm#13-0000 for the position of Top Executives) plus

100 percent for fringe benefits (($59.71 per hour x 40 hours per applicant) * 2), the estimated cost per application is $4,776.80. The total cost burden to respondents or record-keepers resulting from the collection of this information is $152,857.60 (4,776.80 * 32 hospitals).

Most applicants choose the option to purchase Medicare Provider Analysis and Review (MedPAR) data to provide a detailed cost analysis demonstrating they meet the cost criteria. The MedPAR data is available for purchase from the CMS contractor (ResDAC) for $3,600. In the event that all applicants purchase the MedPAR data, we assume an additional burden of $3,600 per applicant for a total additional burden of $115,200 ($3,600 x 32 applications).

This results in a total annual cost burden to respondents or record-keepers of $268,057.60 ($152,857.60 + $115,200).

13. Capital Costs

There are no capital costs.

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 80 to 120 hours per application. We use the midpoint of this range (100 hours) to derive the following estimate.

$44.48/hr (average salary GS 12, 13, 14) X 100 hours / request X 32 applications (midpoint range for potential/projected number of applications 27--36) = $142,336.

15. Changes to Burden

As discussed in section 12 of this document, we have increased the estimated annual number of respondents from 15 to 32. All time and cost burdens have been adjusted accordingly. There are no changes to the requirements associated with this information collection request.

16. Publication/Tabulation Dates

Applications are submitted to CMS in the fall (August through October/November). Once all the New Technology Add-On Payment applications are received by a specified date in October/November, the New Technology Add-On Payment Team, with input from the HAPG Medical Officers, drafts summaries, including CMS' concerns, for each of the New Technology Add-On Payment Applications. Once finalized, each of these written summaries is then published in the Notice of Proposed Rule Making (NPRM).

In the NPRM, we ask for public comments regarding our concerns for each of the new

applications during a 60 day comment period. Once all public comments are received by the close of this comment period, the comments are grouped according to their concerns and input. Subsequently, in the fiscal year's Final Rule, we publish a summarized account of comments for each new technology application. The New Technology Add-On Payment Team and the HAPG Medical Officers also makes a recommendation to CMS and HHS leadership who make a final decision as to whether each new applicant will receive a New Technology Add-On Payment the following fiscal year. We publish these final decisions in the Final Rule.

Also, in each NPRM and final rule, for approximately 2 to 3 years after the applications have been approved, we publish a summary of each of the previously approved applications and ask for public comments as to whether these applications continue to meet the criteria and should receive New Technology payment for an additional year. Applicants do not need to reapply if they had been previously approved.

17. Expiration Date

All forms will be updated with the expiration date once approval has been sought and will be place on the first page of each form.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

There are no statistical methods.