

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) both electronically and in hard copy. 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 32 applications annually. This estimated number of applications is based on the fact the number of applications we receive each year has been increasing in recent years, from less than 10 to 18. We believe that we will continue to receive an increased number of New Technology Add-On Payment applications.

Update:

As discussed in section B.12 of this document, we are revising the estimated annual number of respondents from 32 to 62, due to the adoption of alternative new technology add-on payment pathway for certain devices and certain antimicrobial products in the FY 2020 IPPS final rule (CMS-1716-F; August 16, 2019; 84 FR 422972 - 42297) and the FY 2021 IPPS final rule. We are also revising the time and cost burdens due to the addition of the alternative new technology add-on payment pathway for certain devices and certain antimicrobial products. (We note, there are no changes to the burden for the traditional pathway new technology add-on payment policy.) We are submitting these revisions to the estimate to OMB for review and approval in light of the addition of these alternative pathway for applicants seeking new technology add-on payments.

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 Inpatient Prospective Payment System (IPPS). 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 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.

In the FY 2020 IPPS final rule (84 FR 42292- 42297) and FY 2021 IPPS final rule, we adopted an alternative new technology add-on payment pathway for certain devices and certain antimicrobial products. Specifically, applications received for new technology add-on payments under the alternative pathway will need to meet the cost criterion (that is, the medical product must be costly such that the DRG rate otherwise applicable to discharges involving the medical product is determined to be inadequate). The alternative new technology add-on payment pathway is available:

- (1) Effective for FY 2021, for a medical device that is part of the Federal Drug Administration’s (FDA’s) Breakthrough Devices Program.
- (2) Effective for FY 2021, for a product that is designated by the FDA as a (Qualified Infectious Disease Product (QIDP) and has received FDA marketing.
- (3) Effective for FY 2022, for a product that is approved under FDA’s Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD).

To implement these, we revised the regulations at 42 CFR 412.87.

We use the application in order to determine if a technology meets the new technology criteria under the traditional pathway, and have revised the application to reflect the information required to determine if a device meets the new technology criteria under the alternative pathway for certain devices and certain antimicrobial products.

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.

The regulations at 42 CFR 412.87(b)(3) and 42 CFR 412.87(c) provide 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 under the traditional pathway, 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 5 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 6 through 21 provide information needed to determine the "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 22 through 33 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, Final New Technology Payment Thresholds, issued as part of the annual IPPS final rule.
- Responses to questions 34 through 36 describe how the technology meets the substantial 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 improvement.

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 two hardcopies of the tracking form, completed 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 regulatory requirements. Reducing or eliminating this collection would contradict the regulation.

7. Special Circumstances

Per our application we require that the applicant submit an electronic copy and two hardcopies of their tracking form, completed application, and any supporting documentation they wish to include..

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 Federal Register notice published on August 15, 2019 (84 FR 41723). The 30-day Federal Register Notice Published on December 17, 2019 (84 FR 68936) with no comments received.

9. 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 65 percent (or 75 percent for certain antimicrobial products) 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 65 percent (or 75 percent for certain antimicrobial products) of the estimated costs of the new technology.

10. Confidentiality

As described in section 7 of this document, ‘Special Circumstances’, 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)

In order to receive new technology add-on payments, a technology must meet the criteria set forth in the regulations at 42 CFR 412.87. Responses to the questions in the form help CMS determine if and how the applicant meets the established criteria and to calculate payments for approved technologies. As described in section B.2., “Information Users,” applications will be evaluated against the new technology add-on payment criteria by a CMS team, which include two to three Medical Officers. Applications are submitted in hard copy (one for each Medical Officer) in addition to an electronic copy for the CMS team to thoroughly review the comprehensive and detailed information provided in the application, which includes technically complex research studies and clinical information. These reviews are extensive, taking hours to complete, and many team members, in particular the Medical Officers, find it

difficult to do this on a computer screen. They also make notes, and they often are working offline.

Based on our recent experience, in the next several years we estimate receiving approximately 27 to 36 applications annually under the traditional new technology add-on payment pathway that are evaluated under the criteria in the regulations at 42 CFR 412.87(b). This number of respondents is based on the upward trending number of applications that have been received since the approval of this collection. We chose the average of 32 applications per year for purposes of our estimate in this PRA under the traditional new technology add-on payment pathway. 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 application under the traditional pathway new technology add-on payment policy and our estimate of the number of applications (27 to 36) is realistic if the volume of the recent upward trend remains consistent. We also believe that using the average of 32 applications under the traditional new technology add-on payment pathway for the purposes of this PRA is reasonable.

As described in section 1 of this document, “Need and Legal Basis”, under the traditional new technology add-on payment pathway, there are three criteria for a new medical service or technology to receive the additional payment, which are referred to as newness, cost, and substantial clinical improvement. In the FY 2020 IPPS final rule (84 FR 42292- 42297), we adopted alternative new technology add-on payment pathway for certain devices and certain antimicrobial products which provide that a medical device that has received FDA marketing authorization and that is part of the FDA’s Breakthrough Devices Program or a product has received FDA marketing authorization and is designated by FDA as a QIDP will need to meet the cost criterion (and is not required to meet the newness or substantial clinical improvement criteria under the traditional policy pathway). In the FY 2021 IPPS final rule, we added a new medical product that is approved under FDA’s LPAD pathway to the alternative new technology add-on payment pathway, effective for FY 2022 applications.

Under these alternative new technology add-on payment pathway for certain devices and certain antimicrobial products, based on our recent experience, in the next several years we estimate receiving approximately/potentially 25 to 35 applications annually. We have chosen the average of 30 applications per year under the alternative new technology add-on payment pathway for purposes of this PRA. This estimated number of applications is based on the fact the number of applications for devices we receive each year has gradually been increasing, and there the number of devices that that are part of the FDA’s Breakthrough Devices Program has also been increasing. We believe our estimate of the number of applications under the alternative new technology add-on payment pathway for certain devices and certain antimicrobial products (25 to 35) is realistic based on the recent upward trends, and we believe that using the average of 30 applications under the alternative new technology add-on payment pathway for the purposes of this PRA is reasonable.

With the potential increase in the total number of applications under this collection due to the addition of the alternative new technology add-on payment pathway for certain devices and

certain antimicrobial products, it is necessary to revise the number of respondents and burden estimates since the approval of this collection. As described in section 1 of this document, under the alternative new technology add-on payment pathway for certain devices and certain antimicrobial products, to receive a new technology add-on payment the device or product will need to meet the cost criterion (that is, the medical device or product must be costly such that the DRG rate otherwise applicable to discharges involving the technology is determined to be inadequate); it is not required to meet the “newness” and “substantial clinic improvement” criteria. Therefore, we have adjusted the overall estimate of the number of applicants and revised the burden accordingly.

Traditional New Technology Add-on Payment Pathway: For the traditional new technology add-on payment policy, we estimate the time associated with collecting the information for the application and submitting the data in hard copy and 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 respondent 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) x 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 for traditional new technology add-on payment pathway applications is \$152,857.60 (4,776.80 x 32 hospitals).

Most applicants choose 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).

For the traditional new technology add-on payment pathway, this results in a total annual cost burden to respondents or record-keepers of \$268,057.60 (\$152,857.60 + \$115,200).

Alternative New Technology Add-on Payment Pathway: For the new technology add-on payment pathway, we estimate the time associated with collecting the information for the application and submitting the data in hard copy and electronically to CMS to be 1.25 working days (1.25 days x 8 hours per day = 10 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 DRG information). Once an applicant submits an application to CMS the application is then reviewed by staff at CMS, we estimate an additional 2 to 3 hours per respondent for answering questions and clarifying information related to the cost criterion during the review. Based on the average additional time of 2.5 hours to respond to questions, we estimate 375 total burden hours for the submission of one application (that is 30 applications x 12.5 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 12.5 hours per applicant) x 2), the estimated cost per application is \$1,492.75. The total cost burden to respondents or record-keepers resulting from the collection of this information for alternative new technology add-on payment pathway applications is \$44,782.50 (\$1,492.75 x 30 hospitals).

Most applicants choose to purchase Medicare Provider Analysis and Review (MedPAR) data to provide a detailed cost analysis demonstrating they meet the cost criterion. 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 \$108,000 (\$3,600 x 30 applications).

For the alternative new technology add-on payment pathway, this results in a total annual cost burden to respondents or record-keepers of \$152,782.50 (\$44,782.50 + \$108,000).

In total (for both the traditional and alternative pathway applications), this results in a total annual cost burden to respondents or record-keepers of \$420,840.10 (\$268,057.60 for the traditional new technology add-on payment pathway plus \$152,782.50 for the alternative new technology add-on payment pathway).

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.

For the traditional new technology add-on payment pathway, we estimate the total time to process, evaluate and reach a decision is 80 to 120 hours per application, and we use the midpoint of this range (100 hours) to derive the estimate of the cost to Federal Government. As described in section 12 of this document, we are using an estimate of 32 applications under the traditional new technology add-on payment pathway for the purposes of this PRA.

For the alternative new technology add-on payment pathway, we estimate the total time to process, evaluate and reach a decision is 20 to 30 hours per application, and we use the midpoint of this range (25 hours) to derive the estimate of the cost to Federal Government. As described in section 12 of this document, we are using an estimate of 30 applications under the alternative new technology add-on payment pathway for the purposes of this PRA.

Based on the average salary of personnel primarily engaged in the review, \$44.48/hour (average

salary GS 12, 13, 14), we estimate the cost to Federal Government for the traditional new technology add-on payment pathway is \$44.48/hour x 100 hours x 32 applications or \$142,336. Similarly, for the alternative new technology add-on payment pathway we estimate the cost to Federal Government is \$44.48/hour x 25 hours x 30 applications or \$33,360.

In total (for both the traditional and alternative pathway applications), this results in a total annual estimate the cost to Federal Government of \$175,696 (\$142,336 for the traditional new technology add-on payment pathway plus \$33,360 for the alternative new technology add-on payment pathway).

15. Changes to Burden

As discussed in section 12 of this document, we have increased the estimated annual number of total respondents from 32 to 62, based on adoption of alternative new technology add-on payment pathway for certain devices and certain antimicrobial products. All time and cost burdens have been adjusted accordingly. (Note, there are no changes to the burden for the traditional pathway new technology add-on payment policy.) 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). Once all the New Technology Add-On Payment applications are received by a specified date in October, 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 placed on the first page of each form.

18. Certification Statement

There are no exceptions to the certification statement.