Supporting Statement Part A for Paperwork Act Submissions

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

(CMS-10638; OMB-0938-1347)

A. Background

For consideration for add-on payments for new medical services or technologies for FY 2019 and subsequent Federal Fiscal Years, applicants were required to submit a formal new technology add-on payment (NTAP) application (which included a tracking form) both electronically and in hard copy. The application included 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. For the convenience of the applicants, the application was posted on the CMS website in multiple electronic formats. Applicants were required to submit an electronic copy and hard copy to CMS by the deadline posted on the CMS website. 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*.

Beginning with FY 2024 applications, CMS implemented an electronic application intake system for NTAP applications within the Medicare Electronic Application Request Information System (MEARIS™) in order to make our current application process more efficient. The electronic NTAP application in MEARIS™ used an application/form that was very similar to the previous paper application (CMS 10638) except for a few minor changes to either accommodate the web format or further provide simplification or clarification of the existing application questions. Beginning with FY 2024 applications and for subsequent application cycles, CMS only accepts NTAP applications submitted via MEARIS™. Complete application information, along with final deadlines for submitting a full application, is posted each year on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*.

For FY 2025, we are updating the NTAP MEARIS™ application to further simplify or clarify existing application questions, including: a) reorganizing the Coding, Cost, and Volume sections of the application to improve flow, b) simplifying the FDA section questions and revising language for these questions to reflect policy changes effective for FY 2025, c) simplifying the way applicants can include codes and MS-DRGs, and d) adding additional explanatory notes in multiple sections of the application to improve understanding of the question. We are requesting renewal of PRA approval from OMB by the end of July to meet our statutory rulemaking deadlines.

We estimate receiving approximately 62 applications annually. See the burden estimate

section below for more information.

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 NTAP 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 refer to applications that must meet all three of these criteria as traditional NTAP pathway applications.

In the FY 2020 IPPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS final rule, we adopted an alternative NTAP pathway for certain devices and certain antimicrobial products. Specifically, applications received for new technology add-on payments under the alternative pathway 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). These applications do not have to meet the substantial clinical improvement criterion and therefore do not have to provide this information at the time of application. The alternative NTAP pathway is available:

(1) for a medical device that is part of Federal Drug Administration's (FDA's) Breakthrough Devices Program and that receives marketing authorization as a Breakthrough Device for the indication covered by the Breakthrough Device designation.

(2) for a product that is designated by FDA as a Qualified Infectious Disease Product (QIDP) and that receives marketing authorization for the same indication; and for a product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and that is used for the same indication. To implement these, we revised the regulations at 42 CFR 412.87.

In the FY 2024 IPPS final rule (88 FR 58948 through 58958), we finalized modifications to the NTAP eligibility requirements related to FDA status. Specifically, beginning with FY 2025 applications, for technologies that are not already FDA market authorized, applicants are required to have a complete and active FDA marketing authorization request at the time of NTAP application submission and must provide documentation of FDA acceptance/filing of their FDA application. Technologies must also be

FDA market authorized by May 1 prior to the fiscal year in order to be eligible for consideration for NTAP.

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

2. Information Users

NTAP applications are evaluated by the Division of New Technology (DNT) Team working in collaboration with Medical Officers in CMS. This team reviews each application against the NTAP criteria and provides 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 NTAP 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 NTAP under the traditional pathway, a specific technology must be "new" and demonstrate that they are not substantially similar to existing technologies 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). Alternative pathway technologies must also be "new", but are considered not substantially similar to existing technologies.

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

3. Use of Information Technology

To make our application process more efficient, we have implemented an NTAP module in the Medicare Electronic Application Request Information System™ (MEARIS™) beginning with the applications being evaluated in FY 2024 IPPS rulemaking and for each subsequent year thereafter. Changes to the NTAP application are reflected in the MEARIS™.

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 NTAP. 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 NTAP 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

We require that the application and any supporting documentation be submitted electronically, through MEARIS™. 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.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on 06/27/2023 (88 FR 41632).

No comments received.

The 30-day Federal Register notice published on 09/15/2023 (88 FR).

9. Payments/Gifts to Respondents

NTAP 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

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. We provide the following notes in the Disclaimer section of the application:

> All content submitted as part of this application may be made public unless otherwise noted below. Information that should not be made public is not taken into consideration when determining whether a technology meets the NTAP criteria. Throughout this application, "made public" refers to either posting application materials publicly or including information from an application in our discussion in the Federal Register. If you would like to include information that should not be made public as part of your application, please refer to the "Additional Application Information - CONFIDENTIAL" section on the summary page at the end of the application. Please note that any data provided in this application may become subject to disclosure where required by law. Where CMS has indicated that information won't be made public, CMS will attempt, to the extent allowed by law, to keep that information protected from public view.

11. Sensitive Question

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

Traditional NTAP Pathway: 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.

Based on our recent experience, we estimate receiving approximately 27 to 36 applications annually under the traditional NTAP pathway that are evaluated under the criteria in the regulations at 42 CFR 412.87(b). We chose the average of 32 applications per year for purposes of our estimate in this PRA under the traditional NTAP pathway. We believe that using the average of 32 applications under the traditional NTAP pathway for the purposes of this PRA is reasonable.

For the traditional NTAP policy, Table 1 shows our estimation of the cost and time burden associated with collecting the information for the application to be submitted electronically to

CMS and answering questions. We estimate the time associated with collecting the information for the application electronically to CMS to be 4 working days (4 days x 8 hours per day = 32 hours) **(Step 1)**. 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 **(Step 2)**. The total burden hours for each applicant to fill out the application and answer CMS questions is 40 hours **(Step 3)**. To calculate cost burden for each applicant, we assume a current salary of $62.04 per hour[1], plus 100 percent for fringe benefits (($62.04 per hour x 40 hours per applicant) x 2) **(Step 4)**. This brings the estimated cost per application to $4,963.20 **(Step 5)**. With 32 applications, the total cost burden to respondents or record-keepers resulting from the collection of this information for traditional NTAP pathway applications is $158,822.40 (4,963.20 x 32) **(Step 6)**.

Most applicants choose to purchase Medicare Provider Analysis and Review (MedPAR) data to provide a detailed cost analysis demonstrating they meet the cost criteria. MedPAR data containing information for the largest number of beneficiaries (20+ million) is available for purchase from the CMS contractor (ResDAC) for $5,000.[2] In the event that all applicants purchase the MedPAR data, we assume an additional burden of $5,000 per applicant for a total additional burden of $160,000 ($5,000 x 32 applications) **(Step 7)**.

For the traditional NTAP pathway, this results in a total annual cost burden to respondents or record-keepers of $318,822.40 ($158,822.40 + $160,000) **(Step 8)**.

Table 1. Cost Burden for Information Collection for the Traditional NTAP Pathway

Step	Description	Total
1	Number of burden hours for each applicant to fill out an application (A)	4 workdays x 8 hours/day = 32 hours
2	Number of burden hours for each applicant to answer questions from CMS after submitting application (B)	8 hours
3	Total burden hours for each applicant to fill out application and answer questions (C=A+B)	40 hours
4	For each applicant: Hourly rate (D) Fringe benefit (E) Sum (F=D+E)	 $ 62.04 $ 62.04 $ 124.08
5	Total hourly burden for all applications to fill out application and answer CMS questions (C*32 applications)	1,280 hours
6	Cost burden for each applicant to fill out application and answer CMS questions (G=F*C)	$ 4,963.20

[1] 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 (mean hourly wage).
[2] ResDAC, CMS Fee List for Physical Research Data Request. (price list on ResDAC, accessed 5/1/2023).

7	Total cost burden for all applicants to fill out application and answer CMS questions (G*32 applications)	$158,822.40
8	Total cost burden for all applicants to purchase MedPAR data (H=$5,000*32 applications)	$160,000.00
9	***Total cost burden for all applications (G+H)***	***$318,822.40***

Alternative NTAP Pathway: Based on our experience, we estimate receiving approximately 25 to 35 alternative pathway applications annually. We have chosen the average of 30 applications per year under the alternative NTAP pathway for purposes of this PRA. We believe our estimate of the number of applications under the alternative NTAP pathway for certain devices and certain antimicrobial products (25 to 35) is realistic based on the recent trends, and we believe that using the average of 30 applications under the alternative NTAP pathway for the purposes of this PRA is realistic based on the recent trends.

For the alternative NTAP pathway, Table 2 shows our estimation of the cost and time burden associated with collecting the information for the application to be submitted electronically to CMS and answering questions. We estimate the time associated with collecting the information for the application and submitting the data electronically to CMS to be 1.25 working days (1.25 days x 8 hours per day = 10 hours) **(Step 1)**. 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 2.5 hours on average to respond to questions **(Step 2)**, bringing the total time burden to 12.5 hours) **(Step 3)**. Based on the same assumption of current salary plus 100 percent for fringe benefits as in the traditional pathway **(Step 4)**, the estimated cost per application is $1,551 **(Step 5)**. The total cost burden to respondents or record-keepers resulting from the collection of this information for alternative NTAP pathway applications is $46,530 ($1,551 x 30 applications) **(Step 6)**.

Based on the cost of MedPAR data discussed earlier, in the event that all applicants purchase the MedPAR data, we assume an additional burden of $5,000 per applicant for a total additional burden of $150,000 ($5,000 x 30 applications) **(Step 7)**.

For the alternative NTAP pathway, this results in a total annual cost burden to respondents or record-keepers of $196,530 ($46,530 + $150,000) **(Step 8)**.

Table 2. Cost Burden for Information Collection for the Alternative NTAP Pathway

Step	**Description**	**Total**
1	Number of burden hours for each applicant to fill out an application (A)	1.25 workdays x 8 hours/day = 10 hours
2	Number of burden hours for each applicant to answer questions from CMS after submitting application (B)	2.5 hours
3	Total burden hours for each applicant to fill out	

	application and answer questions (C=A+B)	12.5 hours
4	For each applicant: Hourly rate (D) Fringe benefit (E) Sum (F=D+E)	 $ 62.04 $ 62.04 $ 124.08
5	Total hourly burden for all applications to fill out application and answer CMS questions (C*30 applications)	375 hours
6	Cost burden for each applicant to fill out application and answer CMS questions (G=F*C)	$ 1,551.00
7	Total cost burden for all applicants to fill out application and answer CMS questions (G*30 applications)	$ 46,530.00
8	Total cost burden for all applicants to purchase MedPAR data (H=$5,000*30 applications)	$150,000.00
9	***Total cost burden for all applications (G+H)***	***$196,530.00***

The total hourly burden for all the applicants to fill out and answer questions for their applications is 1,655 hours. This includes a total of 1,280 hours for applications on the traditional pathway and 375 hours for those in the alternative pathway. This results in a total annual cost burden to respondents or record-keepers of $515,352.40 ($318,822.40 for the 32 traditional NTAP pathway plus $196,530.00 for the 30 alternative NTAP pathway).

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

Applications submitted to the CMS team contain increasingly technically complex research studies and clinical information that take hours to review thoroughly. The cost to process the information submitted is estimated as follows based on review by analysts, medical officers, contractors, 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 NTAP pathway, we estimate the total time to process, evaluate and reach a decision is 160 to 240 hours per application, and we use the midpoint of this range (200 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 NTAP pathway for the purposes of this PRA.

For the alternative NTAP 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 30 applications under the alternative NTAP pathway for

the purposes of this PRA.

Based on the estimated average salary of personnel primarily engaged in the review, $71.88/hour (average salary GS 12, 13, 14, 15, medical officers, and contractors) and double the salary for fringe benefits, we estimate the cost to Federal Government for the traditional NTAP pathway is ($71.88+$71.88/hour) x 200 hours x 32 applications or $920,064. Similarly, for the alternative NTAP pathway we estimate the cost to Federal Government is ($71.88+71.88/hour) x 100 hours x 30 applications or $431,280.

In total (for both the traditional and alternative pathway applications), this results in a total annual estimate the cost to Federal Government of $1,351,344 ($920,064 for the traditional NTAP pathway plus $431,280 for the alternative NTAP pathway).

15. Changes to Burden

The goal of the changes to NTAP application in MEARIS™ is to improve efficiency and clarity for applicants and to reduce the need for follow-up with applicants.

For FY 2025, we are updating the NTAP MEARIS™ application to further simplify or clarify existing application questions, including:

a) reorganizing the Coding, Cost, and Volume sections of the application to improve flow,

b) simplifying the FDA section questions and revising language for these questions to reflect policy changes effective for FY 2025,

c) simplifying the way applicants can include codes and MS-DRGs, and

d) adding additional explanatory notes in multiple sections of the application to improve understanding of the question.

These changes will not result in any net increase in burden for applicants.

We have seen an increase in burden for CMS due to the increase in volume of applications and the complexity of those applications, as reflected in the calculations above.

16. Publication/Tabulation Dates

Applications are submitted to CMS in the fall (from August into October). Once all the NTAP applications are received by a specified date in October, the NTAP team, with input from the Medical Officers, evaluates the information contained in the applications, drafts summaries of the information provided by the applicants, drafts CMS' concerns for , for each of the NTAP applications. Once finalized, each of these written summaries is then published in the IPPS Notice of Proposed Rule Making (NPRM) in or around April 1. Beginning with FY 2024 applications, we also publicly post the corresponding NTAP applications (with certain sections removed as indicated in the Disclaimer section of the MEARIS™ application), at the time of the NPRM publication.

In the IPPS 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 IPPS final rule, we publish, by the statutory deadline of August 1st each year, a summarized account of comments for each new technology application. The NTAP team and the Medical Officers also make a recommendation to CMS and HHS leadership who make a final decision as to whether each new applicant will receive NTAP 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 the previously approved applications and ask for public comments as to whether these applications continue to meet the criteria and should receive NTAP for an additional year. Applicants do not need to reapply if they had been previously approved.

17. Expiration Date

The expiration date will be updated in the PRA section of the application in MEARIS™ once approved.

18. Certification Statement

There are no exceptions to the certification statement.