Supporting Statement – Part A

Recognition of Pass-Through Payment for Additional (New) Categories of Devices under the Outpatient Prospective Payment System and Supporting Regulations
(CMS-10052; OMB 0938-0857)

A. Background

For consideration for Outpatient Prospective Payment System (OPPS) Device Pass-through payment status applicants are required to submit a device pass-through payment status application. Beginning in CY 2022, CMS implemented an electronic application intake system for device pass-through applications within the Medicare Electronic Application Request Information System (MEARIS™) to make our application process more efficient. The electronic device pass-through application in MEARIS™ was very similar to the paper application form (CMS-10052, OMB 0938-0857), except for a few minor changes to either accommodate the web format or provide simplification or clarification of the existing application questions. Beginning in CY 2023 and for subsequent application cycles, CMS only accepts device pass-through applications submitted via MEARIS™. Compete application information, along with deadlines for submitting a full application is available on the CMS Web site at: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc.

For CY 2028, we are making non-substantive changes to the approved information collection for the device pass-through application in MEARIS™ to simplify or clarify existing application questions and standardize the way applicants provide required information, including: a) reorganizing the existing application to improve the flow of the application, b) simplifying application questions for clearness, c) including more iterative questions to improve clarity and standardization of applicant responses, d) inserting a data field for applicants to provide their cost threshold calculations, and e) adding explanatory notes in multiple sections of the application to improve understanding of the question.

Based on recent trends in application submission across the add-on payment pathways, including device pass-through, and the number of applications received for CY 2027 to date, we estimate receiving approximately 16 applications annually. See the burden estimate section below for more information.

B. Justification

1. Need and Legal Basis

Section 1833(t)(6)(A)(iv) establishes the criteria for determining the application of this provision to new items. Section 1833(t)(6)(C)(ii) provides that the additional payment for medical devices be the amount by which the hospital's charges for the device, adjusted to cost, exceed the portion of the otherwise applicable hospital outpatient department (OPD) fee schedule amount associated with the device. Section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments.

The regulations at 42 CFR 419.66 implement these provisions and specify the criteria for OPPS Device Pass-through payments: (1) The device must be new; (2) the device must not be described by a previous or existing device pass-through category; (3) the device cost must not be insignificant and must exceed certain thresholds; (4) the device must meet certain eligibility and exclusion criteria; and (5) the device must demonstrate a substantial clinical improvement over existing technologies or treatments.

In the CY 2020 final rule (84 FR 61295), we finalized an alternative pathway for devices that are granted an FDA Breakthrough Device designation and receive FDA marketing authorization for the indication covered by the FDA Breakthrough Device designation. Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet all other eligibility criteria in our regulation at 419.66.

We use the application to determine if a device meets the relevant device pass-through payment status criteria.

2. Information Users

Device pass-through 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 device pass-through criteria and provides recommendations to CMS and HHS leadership for decision. Device pass-through applications are submitted to CMS through a quarterly process; however, all applications are subject to notice and comment rulemaking in the next applicable OPPS annual rulemaking cycle. Per regulation, final determinations of eligibility for device pass-through payment status must go through rulemaking and given the opportunity for the public to comment.

Section 1833(t)(6)(A)(iv) established the criteria for determining transitional device pass-through payment status eligibility. Section 1833(t)(6)(B) required CMS to use categories for the purposes of determining the eligibility of new devices for device pass-through payments, further specifying that no medical device approved for transitional pass-through payments may be described by more than one category. The Act specifies that the criteria must include a test of whether the average cost of devices that would be included in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II). Section 1833(t)(6)(C)(ii) provides that the additional payment for medical devices be

the amount by which the hospital's charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable OPD fee schedule amount associated with the device.

In order to qualify for device pass-through payment status, the device must meet all of the eligibility criteria described in 42 CFR 419.66. The nominated device must be new, not be described by a previous or existing device pass-through category, have a medical device cost that is not insignificant and exceeds certain thresholds, meet certain other eligibility and exclusion criteria, and must demonstrate a substantial clinical improvement over existing technologies or treatments, unless the device is part of the FDA Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the FDA Breakthrough Device designation.

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 devices.

3. Use of Information Technology

To make our application process more efficient, we have created an Additional Device Categories for Transitional Pass-Through Payment Status Under the Hospital Outpatient Prospective Payment System (device pass-through) application module in MEARIS™ beginning the CY 2022, and for each subsequent year thereafter, applications must be submitted via MEARIS™. Changes to the device pass-through 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. Some of the information contained in this collection is similar to that submitted by applicants who apply for HCPCS codes for new items and the Inpatient Prospective Payment System (IPPS) new technology payment. However, our review process entails assigning HCPCS codes to new items if needed. Therefore, the information serves a two-fold purpose and minimizes rather than duplicates information. Additionally, there are substantial differences in the information collected in the IPPS and OPPS applications. Finally, the information for IPPS and OPPS are collected at different periods of time based on the rule cycles, affording the opportunity for updated information to be collected during the separate application processes.

Some of the information submitted in this application is also submitted to FDA. However, again, we believe that there is no duplication of effort as the applicant simply submits their FDA approval letter to CMS. In addition, applicants submit information to FDA years prior to point in time when the device pass-through application is submitted to CMS, as such there may be more recent information available. We are not aware of any interfacing technology that would allow seamless sharing of information regarding the nominate device in a timely fashion with little to no burden on staff.

5. Small Businesses

This information collection will affect small entities such as small device manufacturers that wish to apply for device pass-through payment status. 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 OPPS device pass-through criteria as noted.

6. Less Frequent Collection

This information is collected upon request as needed to comply with statutory requirements regarding the establishment of new device categories. This is not a regularly scheduled information collection. The frequency and timing of information collection is determined individually by interested parties, based on the number of items 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, nor would we be able to make transitional pass-through payments for devices that may be eligible for such payments.

7. Special Circumstances

There are no 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 in the Federal Register on 08/21/2025 (90 FR 40831). No comments were received during the comment period.

The 30-day Federal Register notice published in the Federal Register on 11/20/2025 (90 FR 52406)

9. Payments/Gifts to Respondents

There are no payment or gifts to respondents besides the additional payment that respondents' products could receive through the Medicare claims process if their application meets all required criteria and is subsequently approved.

Device pass-through policy provides additional payment for cases with high costs involving eligible new devices. The payment mechanism is based on the cost to hospitals for the new device. Section 1833(t)(6)(D)(ii) of the Act sets the amount of additional pass-through payment for an eligible device as the amount by which the hospital's charges for a device, adjusted to cost (the cost of the device), exceeds the portion of the otherwise applicable Medicare OPD fee schedule amount (the APC payment amount) associated with the device.

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 device meets the device pass-through 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 Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

Based on our recent experience, we estimate receiving approximately 14 to 18 applications annually for device pass-through determination that are evaluated under the criteria in the regulations at 42 CFR 419.66. We chose an average of 16 applications per year for our estimate in this PRA: 8 applications under the traditional device pass-through pathway and 8 applications under the alternative device pass-through pathway.

To calculate cost burden for each applicant, we assume a current salary of $67.24 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 (mean hourly wage), plus 100 percent for fringe benefits ($67.24 per hour x 16 hours per applicant). This brings the estimated cost per application to $1,075.84 per application. Based on 16 applications, the total cost burden to respondents resulting from the collection of this information for device pass-through pathway applications is $17,213.44 ($1,075.84 x16).

13. Capital Costs

Capital costs are not applicable to this collection.

14. Cost to Federal Government

Applications submitted to the CMS team contain increasingly technically complex research studies, clinical information, and other supporting material that take hours to review thoroughly. In addition, applications are submitted for more complex technologies that require research, analysis, and evaluation. 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, applicant communication to clarify or obtain missing information, required data calculations, database inputs, and conferences with applicants and their representatives.

For the traditional device pass-through pathway, we estimate the total time to process, evaluate and reach a decision is 160 to 220 hours per application, and we use the midpoint of this range (190 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 8 applications under the traditional device pass-through pathway for the purposes of this PRA.

For the alternative device pass-through 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 8 applications under the alternative device pass-through pathway for the purposes of this PRA.

Based on the estimated average salary of personnel primarily engaged in the review, $72.61/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 device pass-through pathway is ($72.61+$72.61/hour) x 190 hours x 8 applications or $220,734. Similarly, for the alternative device pass-through pathway we estimate the cost to Federal Government is ($72.61+72.61/hour) x 100 hours x 8 applications or $116,176.

For both the traditional and alternative pathway applications), this results in a total annual estimate the cost to Federal Government of $336,910 ($220,734 for the traditional device pass-through pathway plus $116,176 for the alternative device pass-through pathway).

The average salary was calculated using the locale adjusted general schedule hourly wages for Washington-Baltimore-Arlington, DC-MD-VA-WV-PA.)

15. Changes to Burden

We have revised this CMS 10052 Supporting Statement for readability and clarity.

There are no changes to burden. The goal of the changes to Device Pass-through application in MEARIS™ is to improve efficiency and clarity for applicants and to reduce the need for follow-up with applicants.

For CY 2028, we are updating the Device Pass-through MEARIS™ application to further simplify or clarify existing application questions, including:

a) reorganizing the Device Info, FDA Info/Newness, Cost Info, Volume and Utilization, and SCI sections of the application to improve flow,
b) simplifying questions to improve clarity,
c) reorganizing the Cost Info section to simplify the way applicants can include cost data,
d) removing questions that are no longer required,
e) including questions in the SCI section to standardize responses for completeness, and
f) 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. The information requested in the application is not new and the information the applicants are required to provide on the application remains the same. We believe that the updates we are making to the application may decrease the burden by providing clearer direction, more iterative and simple questions, and an overall improved standardization of applicant responses.

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. The current version of the Device Pass-through MEARIS™ application results in missing, incomplete, and inaccurate information. To cure application issues and facilitate the required evaluation of the application against the criteria, CMS staff must communicate with the applicant to request clarification or changes to the application. Applicants are then required to make corresponding updates to the application in MEARIS™. The updates to the Device Pass-through MEARIS™ application will hopefully eliminate some of the back-and-forth communication required to obtain complete and accurate device pass-through applications and reduce the burden on both CMS staff and the applicants post application submission.

16. Publication/Tabulation Dates

Applications are submitted to CMS on an ongoing basis throughout the calendar year. Device pass-through applications are evaluated via a quarterly process; however, all applications are subject to notice and comment rulemaking in the next applicable OPPS annual rulemaking cycle. All complete applications received by the first business day of the March quarterly deadline of the current year will be included in the proposed rule for the current rule cycle. Devices that are part of the FDA Breakthrough Devices Program, have received FDA marketing authorization for the indication covered by the FDA Breakthrough Devices designation, and meet the other criteria in the regulation can be approved through the quarterly process (81 FR 79655).

Quarterly Evaluation Process:

Once all of the new device pass-through applications are received by the last business day of

each calendar year quarter, the device pass-through team, with input from the Medical Officers, evaluates the information contained in the applications and makes a determination for each application to preliminarily approve the application on the quarter or defer the application to the next applicable OPPS annual rule for final determination. Applications that receive preliminary approval during the quarterly evaluation process will receive pass-through payment status effective at the start of the next quarter after approval. Applications not approved during the quarterly evaluation process will be deferred to the OPPS annual rule. CMS will make a final determination to continue, approve, or deny each application for device pass-through payment in the applicable OPPS final rule.

Annual Rulemaking:

Once all the device pass-through applications are received by the first business day of the March quarterly deadline for the current year, the device pass-through team, with input from the Medical Officers, evaluates the information contained in the applications, drafts summaries of the information provided by the applicants, and drafts CMS' concerns for each of the device pass-through applications. Once finalized, each of these written summaries is then published in the OPPS Notice of Proposed Rule Making (NPRM) in or around July 1. Beginning with FY 2025 applications, we also publicly post the corresponding device pass-through applications (with certain sections removed as indicated in the Disclaimer section of the MEARIS™ application), at the time of the NPRM publication.

In the OPPS 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 topic.

The device pass-through team and the Medical Officers will make a recommendation to CMS and HHS leadership who make a final decision as to whether each applicant will receive, or continue to receive, device pass-through payments the following calendar year. In the calendar year's OPPS final rule, we publish, by the statutory deadline of November 1st each year, a summarized account of comments for each new device application and the device pass-through payment status final determination for each application.

If a new category is determined to be appropriate, a HCPCS code will be established. It will be included on a list of identified additional pass-through device categories, which is posted on our web site, published in the appropriate program transmittal or Federal Register notice and distributed via program transmittal to CMS contractors.

17. Expiration Date

The expiration date will be displayed on the bottom of the last page of the application form.

18. Certification Statement

There are no exceptions to the certification statement.