Supporting Statement Part A
Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies
(CMS-10511, OMB 0938-1250)

A. Background

This is an extension package. Medicare may provide coverage for certain items and services in FDA-approved Investigational Device Exemption (IDE) studies if certain requirements are satisfied (see section 1862(m) of the Social Security Act, and 42 CFR Subpart B). Throughout this document, the words "trial" and "study" are used interchangeably. The FDA and CMS have an interagency agreement (IAA) whereby for purposes of assisting CMS in determining Medicare coverage of items and services in IDE studies, the FDA places all FDA-approved IDE devices in one of two categories:

- Category A (Experimental) device, which refers to a device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective; or
- Category B (Non-experimental/investigation) device, which refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

Section 1862(m) of the Social Security Act (and regulations at 42 CFR Subpart B (sections 405.201-405.215)) allows for payment of the routine costs of care furnished to Medicare beneficiaries in a Category A IDE study and authorizes the Secretary to establish criteria to ensure that Category A IDE trials conform to appropriate scientific and ethical standards. Medicare does not cover the Category A device itself because Category A devices do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary. Medicare may cover Category B devices, and associated routine costs of care, if the FDA confirms that initial questions of safety and effectiveness of that device type have been resolved, or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type, and the Medicare coverage IDE study criteria in § 405.212 are satisfied.

Under the current (post January 1, 2015) centralized review process, interested parties (such as study sponsors) that wish to seek Medicare coverage related to Category A or B IDE studies have a centralized point of contact for submission, review and determination of Medicare coverage IDE study requests. Providers no longer need to notify individual Medicare Administrative Contractors (MACs) regarding IDE studies for which they plan to submit claims since we will post limited information regarding CMS-approved Category A and B IDE studies on the CMS coverage website. We are encouraging providers to check the CMS Coverage Website to see if an IDE study has been approved for purposes of Medicare coverage before submitting IDE related claims to jurisdictional MACs.

This package does not contain a collection instrument.

B. Justification

1. Need and Legal Basis

Section 1862(m) of the Social Security Act (and regulations at 42 CFR Subpart B (sections 405.201-405.215)) allows for payment of the routine costs of care furnished to Medicare beneficiaries in a Category A IDE trial and authorizes the Secretary to establish criteria to ensure that Category A IDE trials conform to appropriate scientific and ethical standards. By providing Medicare coverage of routine costs in Category A trials, Congress removed a financial barrier that may have discouraged beneficiaries from participating in these trials. It also gives Medicare beneficiaries the potential opportunity to have earlier access to new medical devices.

As part of the CY 2014 Physician Fee Schedule Rule, we modified 42 CFR Subpart B to establish Medicare Coverage IDE study criteria for Category A and B IDE studies and establish a centralized review process. We used our general rulemaking authority (Section 1871 of the Social Security Act) to apply the same Medicare coverage requirements to Category B IDE studies that would be applicable to Category A IDE studies.

In order for CMS (or its designated entity) to determine if the Medicare coverage criteria are satisfied for an IDE submission, as described in our regulations, CMS (or its designated entity) must review the following information:

(1) FDA IDE approval letter;
(2) IDE study protocol;
(3) IRB approval letter (if required);
(4) National Clinical Trials (NCT) number;
(5) Supporting materials, as needed.

2. Information Users

For purposes of Medicare coverage of items and services in Category A or B IDE studies, CMS analysts and medical officers use the materials described above to make decisions about whether a Category A or B IDE submitted study satisfies the following Medicare Coverage IDE study criteria (per 42 CFR Subpart B (sections 405.212):

(1) The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.
(2) The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
(3) The study results are not anticipated to unjustifiably duplicate existing knowledge.
(4) The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.
(5) The study is sponsored by an organization or individual capable of successfully

completing the study.

(6) The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, 812 and 45 CFR part 46.

(7) Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.

(8) The study is registered with the National Institutes of Health's National Library of Medicine's ClinicalTrials.gov.

(9) The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.

(10) The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

3. Use of Information Technology

All submitted documentation should be in electronic form and should be sent to a dedicated CMS electronic mailbox. The information does not require a signature from the device trial sponsors.

4. Duplication of Efforts

Medicare coverage is not a requirement for study sponsors to conduct research. Seeking Medicare coverage related to Category A or B IDE studies is voluntary under existing regulations and will continue to be voluntary under the provisions of the modified rule. For parties seeking Medicare coverage of items and services in IDE studies, certain documents requested by CMS for review, (such as the IDE study protocol, IRB approval letter (if required), and the NCT#) will be readily available to the study sponsor since this information would have been previously requested for review by the FDA. The study sponsor may simply include this material as part of their request. In the course of CMS' review, we may request documentation missing from the request that is necessary for our review.

5. Small Businesses

Some device manufacturers and study sponsors may be small businesses. We believe that by establishing a centralized review process as of January 1, 2015, we reduced the previous burden more than tenfold. Centralizing the submission, review, and determination of Medicare coverage of IDE study requests enhances administrative efficiency for small businesses by eliminating the previous need for duplicative submission of requests to multiple local Medicare contractors by

providers or study sponsors.

6. Less Frequent Collection

Seeking Medicare coverage related to Category A or B IDE studies is voluntary and if this information was collected less frequently, the respondents would have no knowledge of Medicare coverage of items and services in Category A and B IDE studies.

7. Special Circumstances

The documents required by CMS may contain proprietary and trade secret information. CMS will retain the protections in §405.215, Confidential Commercial and Trade Secret Information. We note that section 502(c) of the Act broadly prohibits the disclosure of trade secret and confidential commercial or financial information -- information exempt from public disclosure by the Freedom of Information Act (FOIA) 5 U.S.C. 552(b)(4) outside the Department. This prohibition is found in the devices and regulatory inspections provisions of the Social Security Act, and is not limited to device-related information. This disclosure prohibition also applies to information reported or otherwise obtained by the Department during inspection activities and other activities. This prohibition is interpreted to allow information sharing within the U.S. Department of Health and Human Services only.

Upon CMS approval of a Category A or B IDE study, we will post on the CMS Coverage website and periodically in the Federal Register limited information (study title, sponsor name, NCT number, and the IDE number) supplied by the interested party as part of their Medicare coverage IDE study review request, along with the CMS approval date. We note that the same type of information is currently posted on the CMS Coverage Website for other clinical study approvals related to Medicare coverage under the coverage with evidence development (CED) coverage pathway.

8. Federal Register/Outside Consultation

The 60-Day Federal Register notice published September 19, 2025 (90 FR 45214). CMS received a comment from an individual who suggested the federal government reconsider the proposal to cancel Commercial Driver's License (CDL) and non-CDL licenses to protect CDL holders whose careers, families, and futures depend on this license. CMS thanks the commenter. However, the comment is not related to the information collections that are subject to the Paperwork Reduction Act (PRA).

The 30-Day Federal Register notice published December 29, 2025 (90 FR 61154).

9. Payments/Gifts to Respondents

No payments or gifts will be given to respondents to encourage their response, although their participation does grant the respondents information regarding Medicare coverage of items and services in Category A and B IDE studies.

10. Confidentiality

See Section 7.

11. Sensitive Questions

There are no sensitive questions included within the study.

12. Burden Estimates (Hours & Wages)

Estimate of the hour burden and wages of the collection of information for submitters.

Number of respondents: 118 studies per year.

Frequency of response: Once for each study

Annual hour burden: 1-2 hours per study (the study duration is typically 1-3 years, submission of the documents is only required once)

Since January 1, 2015, when the centralized IDE process was implemented, we have received approximately 1083 IDE studies, averaging 103 per year. Of the 1083 submitted studies, 866 were approved, and 217 submissions we wither disapproved or the sponsor was asked to withdraw the submission because of the lack of sufficient information needed for a complete submission. If the sponsor requests a second review, the documents will have to again be sent and reviewed. We estimate that second reviews happen approximately 15% of the time. Adding that 15% brings the total estimate to approximately 118 submissions per year.

01.2015-07.2025 Submitted IDEs	Average IDEs/ Year	15% Re-submitted IDEs	Estimated Total IDEs/Year
1083	103	15	118

For the most part, the documents are copies of communications between the study sponsor and the FDA. Accordingly, we estimate that it will take 1 to 2 hours for an executive administrative assistant in a medical device company to prepare the require information. We estimate that for 118 requests per year, the total time to be expended by all potential study sponsors is between 118 and 236 hours.

Studies/Year	Estimated Hours/Study	Estimated Total Hours
118	1-2	118-236

To derive average costs, we used data from the U.S. Bureau of Labor Statistics for all salary estimates https://www.bls.gov/oes/tables.htm. The burden associated with the requirements under § 405.211 is the time and effort it would take a study sponsor that is requesting Medicare coverage of an FDA-approved IDE to prepare the following electronic

documents as described in Section 1.

In deriving costs to the public, we used the US Bureau of Labor Statistics May 2024 estimate of $37.05 + 100% in fringe benefits for estimated hourly wage of $74.10 for an executive administrative assistant (occupation code 43-6011). We estimate the cost to be between $8743.80 ($74.10 x118) and $17487.60 ($74.10 x236) per year, for 103 potential IDE study sponsors + a potential 15 additional submissions. If the average time of a study is 2 years, the annualized cost is $8743.80 - $17487.6 for a year's applications or $74.10 - $148.20 per study.

Estimated hourly wage for executive administrative assistant*	Estimated Total Hours	Cost/Study	Estimated cost/Year
$74.10	118-236	$74.10-$148.20	$8743.80-$17487.60

* https://www.bls.gov/oes/tables.htm

13. Capital Costs

We do not anticipate additional capital costs.

14. Cost to Federal Government

We have two GS15-7 employees working 10 hours per week, two GS14-7 employees working 20 hours per week and two GS13-9 employees working 15 hours per week for the IDE team. Given federal holidays, we will use 50 weeks for the year. According to the OPM website chrome-https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2025/general-schedule/, the hourly salaries for the Locality Pay Area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA are:

- GS15-7: $93.53 per hour
- GS14-7: $81.93 per hour
- GS13-9: $73.18 per hour

Calculation:
GS15-7 Employees

- Number of Employees: 2
- Hours per Week: 10
- Weeks per Year: 50
- Hourly Rate: $93.53

Total Cost for GS15-7: 2 * 10 hours/week * 50 weeks/year * $93.53/hour = $93,530

GS14-7 Employees

- Number of Employees: 2
- Hours per Week: 20

• Weeks per Year: 50
• Hourly Rate: $81.93
Total Cost for GS14-7: 2 * 20 hours/week * 50 weeks/year * $81.93/hour = $163,860

GS13-9 Employees
• Number of Employees: 2
• Hours per Week: 15
• Weeks per Year: 50
• Hourly Rate: $73.18
Total Cost for GS13-9: 2 * 15 hours/week * 50 weeks/year * $73.18/hour = $109,770

Total Cost
• GS15-7 Total: $93,530
• GS14-7 Total: $163,860
• GS13-9 Total: $109,770
Grand Total: $367,160

The total cost to the federal government for the IDE team, given the hours worked and the hourly salaries, over 50 weeks is $367,160.

Job Title	GS Level	Hourly pay*	Employee Number	Hours/week	Weeks/Year	Yearly Cost
Evidence Development Division Director;Medical Officer	15-7	$93.53	2	10	50	$93,530
Reviewers	14-7	$81.93	2	20	50	$163,860
IDE Process Managers	13-9	$73.18	2	15	50	$109,770
						$367,160

* https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2025/general-schedule/

15. Changes to Burden

The number of responses increased from116 to 118. The burden hours increased from 232 to 236.

16. Publication/Tabulation Dates

This information is not published or tabulated.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number.

18. Certification Statement

There are no exceptions to the certification statement.

19. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.