Supporting Statement Part A
Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies--Revision of Medicare Coverage (CMS-1600-F)
CMS-10511, OMB 0938-New

Background

Medicare may provide coverage for certain items and services in FDA-approved Investigational Device Exemption (IDE) studies if certain requirements are met (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.

Local Medicare contractors have been responsible for making coverage determinations on all FDA-approved Category B IDE devices and related items and services. Medicare may cover Category B devices, and associated routine costs of care, if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

Local Medicare contractors have differing processes for reviewing Category B IDE studies for purposes of Medicare coverage, which results in inconsistent Medicare coverage across contractor jurisdictions. In seeking and receiving input from stakeholders regarding the existing local Medicare contractor approval process, stakeholders told us that obtaining Medicare coverage related to Category B IDE devices is inefficient and contributes to their reluctance to enroll Medicare beneficiaries in IDE trials and studies, and coverage variability between Medicare contractors made it difficult to conduct national IDE trials.

A. 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, the Congress removed a financial barrier that may have discouraged beneficiaries from participating in these trials. It also gives Medicare beneficiaries the 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 met, 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.
(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 and B IDE studies, CMS scientists and medical officers will use the materials described above to make decisions about whether a Category A or B IDE study meets the following Medicare Coverage IDE study criteria.

(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 materials 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, and the NCT number) will be readily available to the study sponsor since this information would have been previously developed 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, we will reduce the current burden by more than tenfold. Centralizing the submission, review, and determination of Medicare coverage IDE study requests enhances administrative efficiency for small businesses by eliminating the need for duplicative submission of requests to multiple local Medicare contractors by providers and/or study sponsors.

6. Less Frequent Collection

Not applicable.

7. Special Circumstances

The documents required by CMS may contain proprietary and trade secret information. As discussed in the final rule, 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 paradigm.

8. Federal Register/Outside Consultation

The July 19, 2013, proposed rule (78 FR 43282) served as the 60-day PRA notice. While we did not receive any comments on the PRA section, we received 48 comments on the proposed rule from various entities including the medical device industry, academic medical centers, health care systems, consultants, and medical societies. A complete summary and our responses to the public comments received on the proposed rule are included in the preamble to the final rule (see Federal Register, Vol. 78, No. 237; Tuesday, December 10, 2013; pages 74429-74437).

While some commenters expressed satisfaction with the current localized coverage review process, we believe that centralizing the submission, review, and determination of Medicare coverage IDE study requests enhances administrative efficiency by eliminating the need for duplicative submission of requests by providers and duplicative reviews by local Medicare contractors. For example, under existing procedures, each provider that participates in an IDE trial and that anticipates filing Medicare claims must notify the Medicare contractor and furnish the contractor with certain information about the IDE trial. Once the contractor notifies the provider that all required information for the IDE study has been furnished, the provider may bill related Category A or B IDE claims.

Under the centralized review process, interested parties (such as study sponsors) that wish to seek Medicare coverage related to Category A or B IDE studies, will have a centralized point of contact for submission, review and determination of Medicare coverage IDE study requests. Providers will no longer need to notify individual contractors 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 and publish a list of approved trials in the Federal Register. 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 local Medicare contractors.

Some commenters believed that the proposed Medicare coverage requirements duplicated the responsibilities of the FDA (such as review of scientific and ethical standards). In our response, we stated that CMS and FDA operate under different statutory authorities and have distinct authorities and responsibilities. FDA approves IDE studies or trials when, among other things, the risks to the subjects are outweighed by the anticipated benefits and the importance of the knowledge to be gained. For purposes of Medicare coverage, we seek evidence that an item or service is reasonable and necessary. The disease burden borne by elderly individuals and the important health care interventions unique to the Medicare population are important areas of focus for the Medicare program; we would not expect the FDA review to include substantive consideration of these Medicare priorities. Thus, we believe that Medicare coverage standards are needed for IDE studies for which Medicare coverage is sought. We wish to ensure that Medicare beneficiaries who volunteer to participate in studies are protected, that the study design is appropriate to answer questions of importance to the Medicare program, and to ensure that the information gained from important clinical trials could be used to inform Medicare coverage decisions.

There are numerous studies that may be considered scientifically valid but are of little benefit to Medicare beneficiaries or to the Medicare program. We believe that this policy establishes Medicare coverage requirements that need to be met to best support a body of clinical knowledge that is relevant to the Medicare program and its beneficiaries. It is essential that IDE studies where Medicare coverage is sought serve the best interests of the Medicare program and its beneficiaries; and that they be useful in improving healthcare delivery to Medicare beneficiaries, and informing Medicare coverage.

We made modifications to the Medicare Coverage IDE study criteria in response to public comments. Of particular note, we removed proposed criterion 7 (all aspects of the study are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors) since its intent can be largely accomplished by adherence to the other Medicare Coverage IDE study criteria. We removed proposed criterion 8 (the study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements) because the intent is implicit in the remaining CMS coverage criteria and requirements.

We also received comments regarding the criterion related to registration of studies with ClinicalTrials.gov. In summary, we stated in our response that we believe that all studies where Medicare coverage is sought under this policy should be registered with ClinicalTrials.gov. When results reporting is required, it offers an assurance of quality because, generally, public access to information enables a higher level of accountability in the accurate reporting of the clinical study protocol and results, and in the conduct of the trial itself. This accountability derives both from public access to information about studies and from the risk of penalty for submitting false or misleading clinical trial information.

We recognize that, for some studies of unapproved devices, the Food and Drug Administration Amendments Act of 2007 (FDAAA) prohibits the public display of information on registration and results until after the device is approved or cleared for marketing. In the final rule, we revised our regulation to avoid indicating that Medicare coverage of such IDE studies would require public display of all information in ClinicalTrials.gov for these unapproved devices. However, we believe that delayed display for this subset of studies, should the device be cleared or approved for marketing, will not significantly undermine our goals. For some studies, we expect public access to ClinicalTrials.gov data will not be delayed and therefore our requirement will immediately lead to greater public transparency for many of the studies supported by Medicare. For those studies about which information cannot be displayed publicly prior to marketing approval, we believe that the possibility of future public access and the risk of liability for the submission of false or misleading clinical trial information to ClincalTrials.gov remain valuable. Registration with ClinicalTrials.gov also assures that Medicare beneficiaries and their treating healthcare professionals will, for those devices ultimately approved or cleared by FDA, eventually have pertinent information about these IDE studies. We note that clinical trials of devices that register with ClinicalTrials.gov for purposes of this regulation are subject to any applicable requirements under FDAAA. In the final rule, we modified the criteria to simply require registration on ClinicalTrials.gov.

9. Payments/Gifts to Respondents

Not applicable.

10. Confidentiality

See Section 7.

11. Sensitive Questions

Not applicable.

12. Burden Estimates (Hours & Wages)

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

Number of respondents: 240 studies per year.

Frequency of response: Once for each study

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

Over the past 18 years, there have been approximately 4000 IDE studies approved that are potentially coverable by Medicare, averaging to about 222 per year. If the sponsor requests a second review, the documents will have to be sent again. We estimate that this may happen 5-8% of the time. Adding another 8% brings the total estimate of about 240 requests per year.

To derive average costs, we used data from the U.S. Bureau of Labor Statistics for all salary estimates. The salary estimates include the cost of fringe benefits, calculated at 35 percent of salary, which is based on the May 2013 Employer Costs for Employee Compensation report by the Bureau. 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.

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 240 requests per year, that the total time to be expended by all potential study sponsors is estimated to be between 240 to 480 hours.

In deriving costs to the public, we used the Bureau of Labor Statistics May 2012 estimate of $24.14 + 35% in fringe benefits for estimated hourly wage of $32.59 for an executive administrative assistant (occupation code 43-6011). We estimate the cost to be between $7.822 - $15,643 per study, for 222 potential IDE study sponsors + a potential 19 additional submissions. If the average time of a study is 2 years, the annualized cost is $3,911 - $15,643 years applications or $16.30 - $39.59 per study.

13. Capital Costs

    Not applicable.

14. Cost to Federal Government

    None.

15. Changes to Burden

    Not applicable. This is a new collection.

16. Publication/Tabulation Dates

    Not applicable.

17. Expiration Date

    This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

    Not applicable/no exceptions.

B. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.