

Medicare Program

Revised Procedures for Making National Coverage Determinations

A. Background

This collection is required by a notice (78 FR 48164-69) published on August 7, 2013 which delineates the Centers for Medicare & Medicaid Services' (CMS) process for making a national coverage determination (NCD) including information for external parties to submit a formal request for a new NCD or a reconsideration of an existing NCD. An NCD is defined in 1862(l) of the Social Security Act (the Act) as "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title."

This information collection will assist us in obtaining the information we require to make a national coverage determination in a timely manner and ensuring that the Medicare program continues to meet the needs of its beneficiaries.

B. Justification

1. Need and Legal Basis

An NCD is defined in 1862(l) of the Social Security Act (the Act) as "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title." The current NCD process is also based on 1862(l) of the Act, which establishes statutory timeframes and a public comment requirement for NCDs. The 2013 Federal Register notice established the procedures for requesting an NCD or reconsideration of an existing NCD and provides the criteria for what constitutes a complete, formal request and the mechanisms for submitting NCD requests to CMS. Specifically, we state that a formal request for NCD must contain the following:

- A final letter of request that is not marked as a draft, and is clearly identified as "A Formal Request for a National Coverage Determination."
- Scientific evidence to support the request for coverage.
- A full and complete description of the item or service in the request, including the target Medicare population and the medical indication(s) for which it can be used and whether the item or service is intended for use by health care providers or beneficiaries.
- FDA status.
- The Medicare Part A or Part B benefit category or categories in which the requester believes the item or service falls.

More specific detail on what constitutes a complete, formal request can be found in the 2013 Federal Register notice.

2. Information Users

The information will be used by CMS to determine whether to accept or reject the request to open an NCD based upon the criteria outlined in the FR notice. Additionally, once we receive a formal request including adequate supporting documentation, CMS will conduct a thorough evidence review in order to make a determination, based on the evidence presented, to cover or non-cover the item or service.

3. Improved Information Technology

CMS offers a mechanism for electronic submission of NCD requests and supporting information. Additionally, the public also has the option to submit a hard copy request.

4. Duplication of Similar Information

The information we are requiring to support a national coverage determination will vary on an individual basis. In instances where an NCD request duplicates another pending request, we will combine the requests and respond with a single decision. While certain NCD requesters may have submitted similar information for review by the FDA, CMS's review determines whether items and services are reasonable and necessary, while FDA focuses their reviews on safety and efficacy. As such, we do not believe these information collection requirements (ICR) duplicate any other collection of information.

5. Small Businesses

Typically a requester is a Medicare beneficiary, a manufacturer, a physician or a physician professional society. We do not anticipate that small businesses would be affected by this collection; however it is possible since any member of the public can submit an NCD request.

6. Less Frequent Collection

This information is collected when a formal request for a national coverage determination is made. If we determine that the request lacks adequate supporting documentation to enable us to review the service to make a national coverage determination, we will notify the requestor and identify the information that we require to enable us to review the service. We will not accept the request and begin our review process until we have received adequate supporting documentation.

7. Special Circumstances

Once a respondent has submitted a formal request, if we determine that the request lacks adequate supporting documentation to enable us to review the service to make a national coverage determination, we will notify the requestor and identify the information that we require to enable us to review the service.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register Notice was published on June 24, 2016 (81 FR 41307). We

received one public comment from a trade organization. The comment has been addressed.

9. Payments/Gifts To Respondents

There were no payments or gifts to respondents.

10. Confidentiality

This collection is public information. CMS does not assure confidentiality outside of the legal and regulatory boundaries that typically control management and disclosure of confidential information.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimate (Total Hours & Wages)

The burden associated with this requirement is the time and effort necessary to disclose the materials referenced above to CMS. Since the majority of NCD requests are from major medical device manufacturers or physician professional societies, we estimate that on average it will take 40 hours at \$43/hour for a Healthcare Support Worker/Management, Scientific and Technical Consulting Services to provide the materials. Based on our experience over the last several years, we estimate that there will be no more than 30 requests on an annual basis. Annually, we estimate 40 hours per submission at a cost of \$1,720 per organization. In aggregate, we estimate 1,200 hours (40 hours x 30 submissions) at \$51,600 (\$1,720 x 30 submissions).

While an estimate of 40 hours may appear low we believe it to be accurate since many stakeholders meet with CMS on an informal basis prior to submitting a formal request to discuss the information needed for an NCD request. In some instances, and for a subset of topics, stakeholders may have compiled similar information for the FDA approval process.

13. Capital Costs

There are no capital costs.

14. Cost to the Federal Government

There is no cost to the Federal Government.

15. Changes to Burden

The revised burden estimate reflects recent experience with NCD requests which are much lower than previously anticipated. Wage information was updated with the most recent information available from the Bureau of Labor Statistics.

16. Publication and Tabulation Dates

We do not publish information on all of the NCD requests we receive. Upon acceptance of a complete, formal request for an NCD, CMS posts a tracking sheet on its website to announce the opening of our review and allows interested individuals to participate and monitor the progress of our review. This information can be found here:

<https://www.cms.gov/medicare-coverage-database/indexes/nca-open-and-closed-index.aspx>

17. Expiration Date

Since there is no collection instrument, CMS will display the expiration date on the “How to Request an NCD” webpage:

<https://www.cms.gov/Medicare/Coverage/DeterminationProcess/howtorequestanNCD.html>

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

These ICRs do not employ statistical methods.