

Medicare Program

Revised Procedures for Making National Coverage Determinations

(CMS-R-290)

A. Background

This is a reinstatement without change. 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. There is no collection instrument.

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 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. Specifically, CMS staff review the information in the submissions against the detailed criteria for what constitutes a complete, formal request as outlined in the FR notice to ensure all requirements are met. 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 published on September 10, 2024 (89 FR 73420). There were no public comments received.

The 30-day Federal Register notice published on November 29, 2024 (89 FR 94731).

9. Payments/Gifts To Respondents

There were no payments or gifts to respondents. This information is required from stakeholders who request that CMS open an NCD analysis to determine whether they can receive Medicare coverage and payment for their technology.

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. Based on our experience over the last several years, we estimate that there will be no more than 30 requests on an annual basis. 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 to provide the materials. According to the U.S. Department of Labor (https://www.bls.gov/oes/current/oes_nat.htm), the mean hourly wage for a Healthcare Support Worker/Management, Scientific and Technical Consulting Services in 2023 was \$22.23. To account for overhead and benefits we have doubled the mean hourly wage which is equal to \$44.46 (\$44 rounded). Annually, we estimate 40 hours per submission at a cost of \$1,760 per organization. In aggregate, we estimate 1,200 hours (40 hours x 30 submissions) at \$52,800 (\$1,760 x 30 submissions).

Number of responses	Hours per response	Annual hour burden	Cost per response	Annual cost burden
30	40	1,200	\$1,760	\$52,800

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

We anticipate that a Grade 14 Step 1 employee may spend 480 hours a year (30 requests x 16 hours) overseeing this endeavor. The locality adjusted wages for a CMS employee at that Grade and Step is \$139,395 annually or \$66.79 hourly as of 2024. Thus, the annual cost to the Federal government for evaluating NCD requests is \$32,059.

15. Changes to Burden

Wage information was updated with the most recent information available from the Bureau of Labor Statistics (2023, published in 2024). There was no change in burden hours (1,200). The cost changed from \$45,600 to \$52,800.

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.