Medicare Program
Revised Procedures for Making National Coverage Determinations
(OMB Number 0938-0776)

This document contains the information collection requirements for 0938-0776, as listed in the supporting statement for the information collection. There is no prescribed collection instrument; however, respondents must submit the information listed.

In accordance with section IV.B. of this Notice, CMS' Revised Process for Making National Coverage Determinations, we require an individual or entity to make a formal request for a national coverage determination in the following manner:

- The formal request letter must be in writing.
- The formal request letter and supporting documentation must be submitted electronically (unless there is good cause for only a hardcopy submission).
- The requestor must identify the request as a "formal request for an NCD" or a "formal request for reconsideration" and identify the NCD development track chosen (described in detail in section IV.E of this notice).
- The requestor must state the benefit category or categories of the Medicare program to which the requestor believes the item or service applies. Examples of benefit categories may include durable medical equipment, physician services, inpatient hospital services, and diagnostic tests. The requestor may recommend one or more benefit categories for the item or service and must submit supporting documentation justifying the recommendation. We must have all information, both from the requestor and internally, to make a benefit category determination, before the request can be considered complete. If an item or service can fit into more than one benefit category, we have the discretion to assign it to the most appropriate benefit category.
- The requestor must submit adequate supporting documentation along with the formal letter, including the following:
    - A full and complete description of the item or service in question.
    - A specific, detailed description of the proposed use of the item or service, including the target Medicare population and the medical condition(s) for which it can be used.
    - A compilation of the supporting medical and scientific information currently available that measures the medical benefits of the item or service. This may include portions of primary study data that have been separately submitted to the FDA as part of its submission package and are deemed most relevant for our review.
    - If the requestor has submitted an application to the FDA for market approval of the product for which coverage is sought, then a copy of the "integrated summary of safety data" and "integrated summary of effectiveness data," or the combined "summary of safety and effectiveness data," portions of the FDA application should be included in the request for an NCD. These documents will ensure that our review is comprehensive.
    - An explanation of the design, purpose, and method of using the item or equipment, including whether the item or equipment is for use by health care practitioners or patients.
    - A statement from the requestor (in cases in which there is an aggrieved party, the

statement must be from that party) containing the following:

- An explanation of the relevance of the evidence selected.
- Rationale for how the evidence selected demonstrates the medical benefits for the target Medicare population.
- Information that examines the magnitude of the medical benefit.
- Reasoning for how coverage of the item or service will help improve the medical benefit to the target population.
- In the case of an aggrieved party, how that party is "in need" of the item or service.
- A description of any clinical trials or studies currently underway that might be relevant to a decision regarding coverage of the item or service.
- Information involving the use of a drug or device subject to FDA regulation as well as the status of current FDA regulatory review of the drug or device involved. An FDA regulated article would include the labeling submitted to the FDA or approved by the FDA for that article, together with an indication of whether the article for which a review is being requested is covered under the labeled indication(s). (We recognize that the labeling on FDA-approved products sometimes changes. For purposes of our review, we are interested in the labeled indications at the time a requestor submits a formal request. If, during our review, the labeled indication or status of a pending FDA approval or clearance changes, we expect the requestor to notify us.)
- In the case of items that are eligible for a 510(k) clearance by the FDA, identification of the predicate device to which the item is claimed to be substantially equivalent.
- In the case of a request for reconsideration, new evidence supporting the request or an analysis of our earlier decision demonstrating that we materially misinterpreted the evidence submitted with the earlier request.