Medicare Program
Revised Procedures for Making National Coverage Determinations

A. Background

CMS revised the April 27, 1999 notice and published a new notice on September 26, 2003 (68 FR 55634) that described the process we use to make Medicare coverage decisions including decisions regarding whether new technology and services can be covered.

We have made changes to our internal procedures in response to the comments we received following publication of the 1999 notice and experience under our new process. Over the past several years, we received numerous suggestions to further revise our process to continue to make it more open, responsive, and understandable to the public. We share the goal of increasing public participation in the development of Medicare coverage issues. This 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

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.

2. Information Users

Upon receipt of a formal request, and adequate supporting documentation, we will make a determination, based on the evidence presented, to cover the device or service or not to cover the device or service where it is not supported by the medical evidence.

3. Improved Information Technology

Individuals or entities making a formal request may make the request, and provide supporting documentation, via e-mail or diskette, or in certain rare circumstances, via hard-copy.

4. Duplication of Similar Information

The information we are requiring to support a national coverage determination will vary on an individual basis. Where a request duplicates another pending request, we will combine the requests and respond with a single decision. These information collection requirements (ICR) do not duplicate any other collection of information.

5. Small Businesses

Small businesses are not affected by this collection.

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 April 13, 2007.

The notice discussing the revisions was published on September 26, 2003, which was approved in a previous PRA submission.

Solicitation of comments on the information collection is found at 64 FR 22624, which was published April 27, 1999.

Occasionally, issues may be complex or controversial and may involve broad health policy concerns. These issues may require extensive consultation with specialty societies, medical researchers, and others familiar with the service and the evidence presented to support its coverage.

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. We estimate that on average it will take each entity 40 hours to provide the materials and that there will be 200 requests on an annual basis. Therefore, the total annual burden associated with these requirements is 8,000 hours. While an estimate of 40 hours may appear low, given that entities will most likely have already compiled these data to meet the FDA approval process, we believe it to be accurate. We estimate the cost at $80,000 (8,000 hours * $10 per hour).

13. Capital Costs

There are no capital costs.

14. Cost to the Federal Government

There is no cost to the Federal Government.

15. Program Changes

There are no program changes. The revisions that were published in the September 26, 2003 notice was approved in the last PRA submission (see Terms of Clearance).

16. Publication and Tabulation Dates

There are no publication or tabulation dates. However, we will announce on CMS' home page issues under coverage review after a formal request has been made.

17. Expiration Date

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

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.