

OMB control Nos.	Approved CFR sections in title 42, title 45, and title 20 (note: sections in title 45 are preceded by "45 CFR," and sections in title 20 are preceded by "20 CFR")
0938-0897	412.22, 412.533.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3062-N]

RIN 0938-AK61

Medicare Program; Revised Process for Making Medicare National Coverage Determinations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice revises the process we will use to make a national coverage determination for a specific item or service under sections 1812, 1832, 1861, 1862, 1869, and 1871 of the Social Security Act, as revised by sections of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. This notice further clarifies our decision-making process and increases the opportunities for public participation.

EFFECTIVE DATE: This notice is effective on October 27, 2003.

FOR FURTHER INFORMATION CONTACT: Vadim Lubarsky, (410) 786-0840.

SUPPLEMENTARY INFORMATION:

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I. Background

In the April 27, 1999 **Federal Register** (64 FR 22619), we published a notice that announced changes to our internal procedures for developing a national coverage determination (NCD) and making the NCD process more open and understandable to the public. As we strive for continuous improvement of our processes, and in recognition of the changes that section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) requires, we are revising our process for developing an NCD in order to make the process more efficient and ensure that we have access to all relevant information to make fully informed decisions. (BIPA, Pub. L. 106-554, was enacted on December 21, 2000.) The processes described in this notice apply to both scope of benefit and section 1862(a)(1) determinations as defined in the Social Security Act (the Act). This notice replaces the April 27, 1999 notice and will be effective on October 27, 2003. Improvements include the following:

- Updating and organizing the reconsideration process into one section, and distinguishing it from an initial request to make an NCD.
- Defining, streamlining, and organizing the contact/inquiry information into one section.
- Revising, formalizing, and updating the elements that constitute a complete, formal request to reflect best practices.
- Adding a section on information that does *not* constitute a complete, formal request.
- Updating and clarifying the conditions for acceptance of a complete, formal request.
- Making it clear that all evidence currently available must be adequate for us to conclude that the item or service is reasonable and necessary.
- Establishing two main tracks for the initial NCD request. One track is a highly time-structured track only available to aggrieved parties (section IV.E track #2), as defined in section 522 of BIPA. The other track is open to anyone, including aggrieved parties, beneficiaries, and manufacturers, and offers a more collaborative and less time-stringent process (section IV.E track #1).

Historically, we have based our coverage determinations on descriptive information, and scientific and clinical evidence. Under the revised BIPA coverage process, we will continue to use descriptive information, and scientific and clinical evidence as a basis for our coverage determinations.

II. Purpose of This Notice

This notice outlines the process we will use to make an NCD under the Medicare program. It sets forth the steps we are taking to make the NCD process more efficient, while maintaining as open and transparent a process as appropriate. It describes the following:

- A tracking system that provides public notice of our acceptance of a complete, formal request and subsequent actions in a web-based format.
- The process we will institute to afford notice and opportunity to comment before implementation of an NCD.
- Information that does and does *not* constitute a complete, formal request.
- The process for asking us to reconsider an existing NCD based on new information, including new medical or scientific evidence.
- The basis and purpose of a decision memorandum and where it can be accessed on our Web site.
- The revisions made to the NCD process under BIPA, including a response to public comments, and how these revisions affect the current NCD process and any subsequent challenges to an NCD.

In addition, we will continue to pursue an ongoing effort to work with various sectors of the scientific and medical community to develop and publish on the CMS Web site documents that describe our approach when analyzing scientific and clinical evidence to develop an NCD. Interested parties will be able to offer comments. Accordingly, these documents will make our coverage process more open and offer the public a better understanding into our NCD process.

In our April 1999 notice, we announced that we anticipated publishing a final coverage criteria rule that would be followed by sector-specific guidance documents (64 FR 22620). Since then, we published a notice of intent to engage in rulemaking for coverage criteria (May 16, 2000, 65 FR 31124) and had a subsequent town