

II. Provisions of the Proposed Notice

A. Proposed Process for Code Maintenance

In the preamble of the November 23, 2001, final rule (66 FR 58788), we announced that we intended to conduct maintenance of the 23 laboratory NCDs and create new laboratory NCDs through the NCD process described in the general notice in the **Federal Register** on April 27, 1999 (64 FR 22619). This process has since been updated by general notice published on September 26, 2003 (68 FR 55634). This is an evidence-based method in which determinations are made based on the scientific literature. Formal requests for an NCD must be made in the following manner:

- The request must be in writing.
- The request and supporting documentation must be submitted electronically unless there is good cause for only a hardcopy.
- The requestor must identify the request as a "formal request for a national coverage" determination.
- The requestor must state the Medicare benefit category.
- The requestor must submit adequate supporting documentation including:

- A full and complete description of the item or service in question;
- A compilation of the medical and scientific information currently available that measures the medical benefits of the item or service;
- 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;
- An explanation of the design, purpose, and method of using the item or equipment;
- A description of any clinical trials or studies currently under way, which might be relevant to a decision; and
- The status of current Food and Drug Administration (FDA) administrative proceedings concerning a drug or device or a service using a drug or device subject to regulation by the FDA.

We continue to believe that this NCD process is appropriate for creating new NCDs for clinical diagnostic laboratory services. Likewise, the NCD process is appropriate for requests for substantive changes to the existing laboratory NCDs. However, we believe this process is unduly burdensome and time-consuming for correcting errors in coding and for incorporating new codes and coding changes that may be created by the ICD-9-CM Coordination and

Maintenance Committee or the AMA Editorial Panel. Likewise, we believe that a streamlined process is appropriate for making coding changes that flow from the existing narrative. Since the narratives only describe covered conditions this abbreviated approach may be used in moving codes from the "Does Not Support Medical Necessity" list (which can be covered with documentation) to the ICD-9-CM codes covered by the Medicare list. "ICD-9-CM Not Covered by Medicare" list cannot be altered through this abbreviated process. Thus, we are proposing two additional processes for making requests for coding changes in the laboratory NCDs.

We are proposing, therefore, to have three separate processes for requesting changes to the laboratory NCDs. Substantive changes would use the normal evidence-based NCD process. Clerical changes to codes and descriptors would be requested, as set forth below, by a letter that outlines the coding change made subsequent to the publication of the NCD or coding error. Coding changes that flow from the narrative covered indications would be requested by letter detailing the covered indication from the narrative. Scientific evidence would not be required, but is welcomed to support the requestor's position.

1. Clerical Coding Change

Coding changes are made annually to both the ICD-9-CM diagnosis codes and the CPT procedure codes that may be incorporated in the laboratory NCDs. Whenever coding changes to codes or descriptors that are included in the NCD are made, we believe the NCDs should be updated expeditiously to reflect current coding practices. Similarly, clerical errors, such as typographical errors, should be corrected as quickly as possible. Consequently, we are proposing a streamlined process for making clerical changes to codes contained within the laboratory NCDs. We propose the following procedures:

- Whenever we discover truncated codes (that is, ICD-9-CM codes that were not displayed to their highest level of specificity), we would expand the code to the full number of digits. We would use the expanded code that most closely matches the ICD-9-CM descriptor displayed in the NCD.
- Whenever an ICD-9-CM or CPT code had been altered (that is, the descriptor was changed) by the responsible coding authority, we would make corresponding changes to the laboratory NCDs.
- Whenever the responsible coding authority deletes an ICD-9-CM or CPT

code, we would remove the code from the NCD. We would not consider this as removal of coverage and would not first publish notice of removal of coverage before taking action.

- Whenever the responsible coding authority changes or replaces an ICD-9-CM or CPT code, we would make corresponding changes to the laboratory NCD based on the crosswalk announced by the coding authority.

- Whenever an ICD-9-CM or CPT code and its descriptor do not match (that is, the descriptor in the NCD is not the descriptor of the code in the coding manuals), we would look to the NCD narrative to determine which item (the code or descriptor) was correct and adjust the other item to match.

- Whenever the responsible coding authority adds a new code to a range of covered codes, we would revise the NCD to include this code.

We are proposing that the general public request clerical or ministerial changes by sending a letter to: Director, Coverage and Analysis Group, Mail Stop C1-09-06, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. In addition, we may initiate changes that we discover. We would incorporate all of these changes into the edit module software and announce them in the coding manual that we publish on the Internet at <http://www.cms.hhs.gov/ncl/labindexlist.asp#coding>.

We believe that the clerical nature of the changes makes public comments on these changes before implementation unnecessary. A method of recognizing necessary coding changes more rapidly would increase payment efficiency and accuracy. We believe that the urgent need to implement these clerical changes into the laboratory NCDs outweighs the benefit that could be derived from requesting public comment on these ministerial changes. Instead, we would accept comments that are generated from these clerical changes through the comment process described below.

2. Codes That Flow From the Covered Indications Narrative

We have received several requests for a procedure to make changes to the codes in the various laboratory NCD code lists by a process other than the NCD process. Many laboratories believe that there have been omissions of codes from the code lists. However, they believe that the current process of gathering scientific evidence to support coverage of a specific code is unduly burdensome and unnecessary since the narrative already includes coverage of the substance of the code description. Therefore, we propose to establish an