

abbreviated process for handling requests for certain coding changes to the laboratory NCDs. In order for requests to qualify for this process, the code must flow from the existing narrative indications for the clinical diagnostic laboratory test. In other words, the requested change must be classified as a replacement of or an addition to an existing code. Requests that in effect constitute requests to add new indications must use the NCD evidence-based process outlined in the September 26, 2003, **Federal Register**. Thus, any requests to cover codes that are in the list of ICD-9-CM Codes Not Covered by Medicare must use the NCD evidence-based process.

The abbreviated process is similar to the NCD process in that it includes posting on the Internet and an opportunity for public comment before making a coding change. The principal difference between the processes is the volume of information required. Requesters using the abbreviated process would submit a letter detailing the provision of the NCD narrative that clearly indicates coverage for the requested code. Scientific literature is not required. However, scientific literature supporting the request and/or clinical guidelines from relevant healthcare organizations is welcome. We are proposing the following abbreviated process for coding changes that flow from the existing narrative of the NCD:

- Requests must be made in writing, clearly stating the rationale for the coding change.
- Requests must be sent to: Director, Coverage and Analysis Group, Centers for Medicare & Medicaid Services, C1-09-06, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.
- Our staff will review the request and contact the requestor for additional information, if necessary.
- We will announce on the Internet (<http://cms.hhs.gov/coverage>) any proposed coding changes. The announcement will provide for a 30-day public comment period.
- Within 60 days of the end of the comment period, we would publish a decision memorandum on the coverage website including a summary of comments received, that announces the decision we intend to issue, and a brief explanation for the determination, if not self-evident, in the request. Within 60 days after posting the decision memorandum, we would publish the decision as an instruction in a One Time Notification that includes the effective date of any changes. Codes that are removed from the covered list as a result of this process because they do not flow

from the narrative would not be subject to additional prior notice of removal of coverage.

- We would incorporate coding changes into the software and coding manual. Coding changes would be made effective on a quarterly basis.

We would, whenever we become aware of the need to do so, also follow this process to implement the necessary changes. We specifically solicit comments on this streamlined process for making coding changes.

In summary, we are proposing three separate processes for maintaining the laboratory NCDs. Clerical and ministerial changes would be made expeditiously without prior posting on the Internet or public comment. Clerical changes would be announced in a CMS instruction before incorporation into the edit software. Coding changes that flow from the narrative of the existing NCD would be handled through an abbreviated process similar to the NCD process. Requests for coding changes that flow from the existing narrative NCD would not require scientific evidence. We would post a notice of this type of request on the Internet and accept public comments for 30 days before making a determination. Requests for a substantive change to an NCD would be handled through the normal NCD process described in the September 26, 2003, **Federal Register**. The requests require scientific evidence in support of the change in policy. We will post a tracking sheet announcing our acceptance of a request on the Internet and public comments will be solicited for 30 days before making a determination.

3. Code Lists for the Laboratory NCDs

We have generally published NCDs in the Medicare Coverage Issues Manual (CIM). This manual is being replaced by the National Coverage Determination (NCD) Manual. We have published some NCDs initially as a Program Memorandum but subsequently have moved the instruction to the CIM. However, we have not, up to this time, published NCDs that contained the detailed coding information that is contained in the clinical diagnostic laboratory service's NCDs that were negotiated.

The clinical diagnostic laboratory NCDs include long lists of ICD-9-CM codes, coding guidelines, and reasons for denial, resulting in a document of approximately 200 pages. Incorporation of this new style arising exclusively from the laboratory negotiated rulemaking process of NCD into the NCD Manual would dwarf the rest of the manual.

We are proposing to incorporate in the NCD Manual only the narrative portion of the NCDs. That is, we would include in the NCD Manual the description of the service, indications, and limitations. We are proposing that the coding lists and standardized portions of the NCDs would be displayed in a laboratory NCD Coding Manual that would be available electronically on the Internet at <http://www.cms.hhs.gov/ncd/labindexlist.asp#coding>. Printed copies can be made available to readers who do not have access to the Internet for a fee of 10 cents per page.

We believe this mechanism would make handling the NCD Manual easier for all users. Users could readily identify those conditions covered without having to weed through long documents with extensive lists of codes. In addition, we believe separating the coding information from the narrative policy helps to reinforce the differing procedures for substantively changing, as opposed to updating, coding in the NCDs.

In summary, we are proposing a streamlined method of updating the NCDs for coding changes of a clerical nature, that is, correcting errors, and accommodating annual coding updates. We are also proposing to publish only the narrative portion of the laboratory NCDs in the NCD Manual, the document where NCDs are normally compiled. The entire laboratory NCDs, including the code lists and coding guidelines, would be published in an electronic laboratory NCD Coding Manual that would be available on the Internet, and upon request, in printed form for a fee. We request public comment on these proposals.

B. Date of Service

In the final rule of coverage and administrative policies for clinical diagnostic laboratory services that we published on November 23, 2001, we clarified the date of service for clinical diagnostic laboratory services (66 FR 58792). Specifically, we stated that: "For laboratory tests that require a specimen from stored collections, the date of service should be defined as the date the specimen was obtained from the archives."

The final rule did not further define how long a specimen must be stored before it is considered "archived." We clarified in Program Memorandum AB-02-134, that in the absence of specific instructions issued nationally through rulemaking, contractors have discretion in making determinations regarding the length of time a specimen must be stored to be considered "archived." We