

stated, however, that the rule contemplates a long storage period.

We have received numerous requests from laboratories to issue a national standard to clarify when a stored specimen can be considered "archived." Regional laboratories interact with numerous contractors and find it difficult to automate their electronic billing software to handle variability in date of service by contractor jurisdiction. In other words, it is difficult for laboratories to electronically program their systems to calculate the date of service when in one jurisdiction it would be the collection date while in another the date of service would be the day that the specimen was retrieved from storage.

Consequently, we are proposing to further clarify the date of service provision for clinical diagnostic laboratory services. We propose that a specimen must be stored for more than 30 calendar days to be considered "archived." The date of service for these archived specimens would be the date the specimen was obtained from storage. Specimens stored 30 days or less would have a date of service of the date the specimen was collected.

The final rule also clarified that the date of service for tests when the collection spanned more than 24 hours would be the date the collection began. These extended collection periods are common on fecal occult blood tests and urine collections for hormone analysis in pregnant women. This clarification was added in the November 23, 2001, final rule in response to public comments received on the March 10, 2000, proposed rule. Thus, we did not have the benefit of public input regarding the appropriateness of our solution.

We have received several comments since issuing the final rule that stated the common practice in the laboratory community is to use the date the collection ended as the date of service. Thus, we are soliciting public comment on a proposal to alter our policy to specify that the date of service for collections that span more than 24 hours would be the date the collection ended.

III. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information

collection should be approved by OMB, section 3506(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comments on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information collection burden on the affected public, including automated collection techniques.

In summary, we propose to establish a new process for handling requests for certain coding changes to the laboratory NCDs. In order for requests to qualify for this process, requests must be made in writing to us, clearly stating the rationale for the coding change. The request must articulate the code flow from the existing narrative indications for the clinical diagnostic laboratory test. In other words, the requested change must be classified as a correction, updating change, or replacement to an existing code. Requests that in effect constitute requests to add new indications must use the NCD evidence-based process outlined in the April 27, 1999, and subsequent September 26, 2003, **Federal Registers**.

The burden associated with the process referenced above is the time and effort necessary to submit a request in writing, clearly stating the rationale for the coding change. We believe that it will require one hour per request and that eight requests will be submitted on an annual basis.

In order to have this requirement approved under the PRA, we will amend the currently approved NCD/PRA documentation [OMB PRA approval # 0938-0776] to include the new code updating process and resubmit it to OMB for approval. We believe that this abbreviated process is less burdensome than the current process. The current process requires submission of scientific evidence in order to initiate a change in the NCD. This abbreviated process requires only an explanation of how a code flows from the narrative.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Julie Brown—CMS-3119-PN, Room C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this notice, and, if we proceed with a subsequent document, *we will respond to the comments in the final rule.*

V. Regulatory Impact Statement

In this notice, we propose an abbreviated mechanism for making changes to the lists of ICD-9-CM and CPT codes that are included in the laboratory NCDs. We also propose clarification of when a specimen is considered archived for purposes of the date of service provision contained in the November 21, 2001, final rule. We do not expect this document to impose any significant burden on laboratories. The proposed policy clarifications may lessen the burden on laboratories by establishing uniform procedures for reporting date of service on archived specimens. Should there be any unanticipated increase or decrease of burden, the effects will be minimal.

We have examined the impacts of this proposed notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternative and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We have reviewed this proposed notice and have determined it is not a major rule. Therefore, we are not required to perform an assessment of the costs and savings.