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'')
0938–0761	484.11, 484.20
0938–0763	422.1–422.10, 422.50–422.80, 422.100–422.132, 422.300–422.312, 422.400–422.404, 422.560–422.622
0938–0768	417.800–417.840
0938–0770	410.2
0938–0778	422.64, 422.111, 422.560–422.622
0938–0779	417.126, 417.470, 422.64, 422.210
0938–0781	411.404–411.406, 484.10
0938–0786	438.352, 438.360, 438.362, 438.364
0938–0787	406.28, 407.27
0938–0790	460.12, 460.22, 460.26, 460.30, 460.32, 460.52, 460.60, 460.70, 460.71, 460.72, 460.74, 460.80, 460.82, 460.98, 460.100, 460.102, 460.104, 460.106, 460.110, 460.112, 460.116, 460.118, 460.120, 460.122, 460.124, 460.132, 460.152, 460.154, 460.156, 460.160, 460.164, 460.168, 460.172, 460.190, 460.196, 460.200, 460.202, 460.204, 460.208, 460.210
0938–0792	491.3, 491.8, 491.11
0938–0798	413.24, 413.65, 419.42
0938–0802	419.43
0938–0810	482.45
0938–0819	45 CFR 146.121
0938–0823	420.410
0938–0824	440.10, 482.13
0938–0827	45 CFR 146.141
0938–0829	422.568
0938–0832	Part 489
0938–0833	483.350–483.376
0938–0841	431.636, 457.50, 457.60, 457.70, 457.340, 457.350, 457.431, 457.440, 457.525, 457.560, 457.570, 457.740, 457.750, 457.810, 457.940, 457.945, 457.965, 457.985, 457.1005, 457.1015, 457.1180
0938–0842	412, 413
0938–0846	411.1, 411.350–411.357, 424.22
0938–0857	Part 419
0938–0860	Part 419
0938–0866	45 CFR Part 162
0938–0872	413.337, 483.20
0938–0873	422.152
0938–0874	45 CFR Parts 160 and 162
0938–0878	Part 422 Subparts F and G
0938–0883	45 CFR Parts 160 and 164
0938–0887	45 CFR 148.316, 148.318, 148.320
0938–0897	412.22, 412.533

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3119–PN]

RIN 0938–AM36

Medicare Program; Procedures for Maintaining Code Lists in the Negotiated National Coverage Determinations for Clinical Diagnostic Laboratory Services

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

ACTION: Notice of proposed procedures for code maintenance.

SUMMARY: This proposed notice would establish the procedures for maintaining the lists of codes that were included in the national coverage determinations (NCDs) that were announced in the final rule published in the **Federal Register** on November 23, 2001 (66 FR 58788). It also sets forth the circumstances in which a laboratory is permitted to use the date the specimen was retrieved from storage for testing as the date of service instead of the date of collection. The proposed notice clarifies the meaning of the ''date of collection.'' In this proposed notice, we propose a standard time frame that would define when a specimen has been ''archived'' for undetermined later use.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 23, 2004.

ADDRESSES: In commenting, please refer to file code CMS–3119–PN. Because staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail.

Mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3119–PN, P.O. Box 8011, Baltimore, MD 21244–8011. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses: Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Jackie Sheridan-Moore, (410) 786–4635.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–9994.

I. Background

A. Current Statutory Authority and Medicare Policies

Sections 1833 and 1861 of the Social Security Act (the Act) provide for payment of, among other things, clinical diagnostic laboratory services under Medicare Part B. Diagnostic tests must be ordered either by a physician, as described in 42 CFR 410.32(a), or by a qualified nonphysician practitioner, as described in § 410.32(a)(3). Tests may be furnished by any of the entities listed in § 410.32(d). A laboratory furnishing tests on human specimens must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578) enacted on October 31, 1988, as implemented by the regulations set forth at 42 CFR part 493. Part 493 applies to all laboratories non-exempt and non-excepted that test human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings. Section 1862(a)(1)(A) of the Act generally provides that no Medicare payment may be made for expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Moreover, section 1862(a)(7) of the Act excludes coverage for routine physical checkup expenses, eyeglasses (other than eyewear described in section 1861(s)(8) of the Act), or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses. In addition, the Act excludes coverage for procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefore, or immunizations (except as otherwise allowed under section 1861(s)(10) and subparagraphs (B), (F), (G), or (H) of paragraph (1)). Under the above statutory authority, we have issued national coverage determinations and policies in a variety of documents, such as CMS (formerly HCFA) manual instructions, **Federal Register** notices, and CMS (formerly HCFA) Rulings. Medicare program manuals, program transmittals, and program memoranda are posted on the Internet at *http://cms.hhs.gov/manuals/default.asp.*

Under section 1842(a) of the Act, we contract with organizations to perform bill processing and benefit payment functions for Medicare Part B (Supplementary Medical Insurance). These Medicare contractors, who process Part B claims from noninstitutional entities, are called carriers. Under section 1816(a) of the Act, we contract with fiscal intermediaries to perform claims processing and benefit payment functions for Medicare Part A (Hospital Insurance). Fiscal intermediaries also process claims payable from the Medicare Part B trust fund that are submitted by providers that participate in Medicare Part A, such as hospitals and skilled nursing facilities. We use the term ''contractor(s)'' to mean carriers and fiscal intermediaries.

Medicare contractors review and adjudicate claims for services to ensure that Medicare payments are made only for services that are covered under Medicare Part A or Part B. In the absence of a specific national coverage determination, coverage decisions are made at the discretion of the local contractors.

B. Recent Legislation

Section 4554(b)(1) of the Balanced Budget Act of 1997 (BBA), Pub. L. 105–33, enacted on August 5, 1997, mandates use of a negotiated rulemaking committee to develop national coverage and administrative policies for clinical diagnostic laboratory services payable under Medicare Part B by January 1, 1999. Section 4554(b)(2) of the BBA requires that these national coverage policies be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory services payable under Medicare Part B.

As directed by this statutory provision, we convened a negotiated rulemaking committee that developed recommendations for coverage and administrative policies in accordance with the provisions of the BBA. On March 10, 2000, we published a proposed rule (65 FR 13082) proposing to adopt the committee's recommendations. The final rule was published on November 23, 2001 (66 FR 58788).

C. National Coverage Determinations (NCDs)

The final rule on coverage and administrative policies for clinical diagnostic laboratory services included an addendum containing NCDs for 23 clinical diagnostic laboratory tests. These NCDs state our policy with respect to the circumstances under which the test(s) will be considered reasonable and necessary for Medicare purposes.

NCDs are binding on all Medicare carriers, intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans (*see* section 1869(f)(1)(A)(i) of the Act).

In accordance with the recommendations of the negotiated rulemaking committee, we developed these clinical diagnostic laboratory NCDs in a prescribed format. Each NCD has the following sections: the official title of the NCD, other names/abbreviations, description, Healthcare Common Procedure Coding System (HCPCS) codes, indications, limitations, International Classification of Diseases, Ninth Edition, Clinical Modification (ICD–9–CM) codes covered by the Medicare program, reasons for denial, ICD–9–CM codes denied, ICD–9–CM codes that do not support medical necessity, sources of information, coding guidelines, documentation requirements, and other comments.

For each of the clinical diagnostic laboratory service NCDs (laboratory NCDs), every ICD–9–CM diagnosis code falls into one of the three code lists. The list of covered codes is intended to reflect the coding translation of the conditions enumerated in the narrative indications section of the NCDs. The translation of the narrative to the appropriate ICD–9–CM diagnosis codes ensures national uniformity in the processing of claims for these clinical diagnostic laboratory tests.

On April 27, 1999, we published a general notice (64 FR 22619) outlining our procedures for developing and revisiting NCDs (the NCD process). We further updated the NCD process in a notice published in the **Federal Register** on September 26, 2003 (68 FR 55634). In the November 23, 2001 final rule (66 FR 58793) for coverage and administrative policies for clinical diagnostic laboratory services, we stated that we would use the NCD process for making changes to the laboratory NCDs. The NCD process is evidence-based and provides an opportunity for public

participation in the NCD decision-making process through the posting of announcements of issues under review on the Internet on the CMS coverage home page and requests for comment. At the conclusion of the NCD decision-making process, decision memoranda are published on the CMS website that announce the policy we intend to issue and discuss the evidence we evaluated and our rationale for the final national coverage determination. Coverage issues are announced at *http://cms.hhs.gov/coverage.*

Under the November 23, 2001 final rule (66 FR 58793), code lists can only be modified through the NCD process. However, subsequent experience with the code lists has indicated that processes for routine changes are necessary. For example, experience with the code lists has revealed that clerical errors occasionally occur despite rigorous review. In addition, the committees that maintain the laboratory and related code lists (ICD–9–CM and CPT–4) routinely issue changes that modify laboratory coding procedures. As a result, the code list for a laboratory NCD may not reflect the most current coding practices. For these reasons, HHS is pursuing new processes in this proposed notice to update code lists for clerical or routine changes.

D. Updates of Coding Systems

1. ICD–9–CM Codes

International Classification of Diseases, Ninth Edition, Clinical Modification (ICD–9–CM) codes were developed in 1977 as a means of classifying morbidity data for indexing medical records, medical case reviews, and ambulatory and other medical care programs, as well as for basic health statistics. It delineates the clinical picture of each patient, providing information beyond that needed for statistical groupings and analyses of healthcare trends. Early in its history, ICD–9–CM coding was used almost exclusively in institutional settings, such as hospitals. However, since 1989, § 424.32(a)(2) has required the reporting of ICD–9–CM coding on all bills for physicians' services. Thus, ICD–9–CM has come into nearly universal use as a means of reporting diagnoses for patients receiving healthcare services.

In September 1985, the ICD–9–CM Coordination and Maintenance Committee (the Committee) was formed. This is a Federal interdepartmental committee, co-chaired by CMS and the National Center for Health Statistics (NCHS), and charged with maintaining and updating the ICD–9–CM system. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD–9–CM to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The Committee encourages participation in the above process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as physicians, medical records administrators, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations that must be approved by the agencies.

ICD–9–CM coding updates are issued annually. Changes become effective October 1 of each year. Minutes from the ICD–9–CM Committee meetings are available on the Internet at *http://cms.hhs.gov/paymentsystems/icd9.* We announce the annual ICD–9–CM procedure coding changes in the **Federal Register** as part of the annual update of the hospital inpatient prospective payment system. In addition, information on the diagnosis coding changes is available on the Internet at *http://www.cdc.gov/nchs/icd9.htm.*

2. CPT–4 Coding

The Current Procedural Terminology (CPT), Fourth Edition, is a listing of descriptive terms and identifying codes for reporting medical services and procedures performed by physicians. The purpose of the terminology is to provide consistent codes for medical, surgical, and diagnostic services.

CPT descriptive terms and identifying codes currently serve a wide variety of important functions in the field of medical nomenclature.

The American Medical Association (AMA) owns CPT. AMA convenes the CPT Editorial Panel (the Panel) quarterly to consider requests and suggestions for changes to CPT. The Panel uses the services of an Advisory Committee with expertise in a wide variety of specialties. Portions of CPT panel meetings are open to the public for the opportunity to make presentations and participate in open discussions. Decision-making sessions, however, are closed. More information regarding the CPT Editorial Panel is available on the following Internet Web site: *http://www.ama-assn.org/ama/pub/category/3884.html.* CPT coding changes are announced annually. Category I changes become effective on January 1 of each year.

E. Implementation of NCDs

One of the goals of section 4554 of the BBA was to promote uniformity in Medicare processing of claims for clinical diagnostic laboratory services. In order to ensure consistent and uniform implementation of the laboratory NCDs throughout the country, we developed an electronic edit table module that will be installed in each of the Medicare claims processing contractors' systems. The edit module will ensure that (1) each contractor matches diagnosis to procedures in the same manner; (2) competing laboratories in an area will have their claims processed identically regardless of whether they are processed by the carrier or fiscal intermediary; and (3) all local contractors have implemented the laboratory NCDs at the same time.

Professional coders on the negotiated rulemaking committee assisted in the development of the laboratory NCDs. Also, we presented the proposed code list to the staff in the Department of Health and Human Services and the general public for review. Nevertheless, we have discovered clerical errors in the code lists. For example, several of the codes did not include the full range of digits. That is, a code that requires 5 digits may have had only 4 digits. We identify this problem by the term ''truncated codes.'' The issue of truncated codes is particularly problematic because our claims processing systems already include edit programs that will return claims to the biller when codes are incomplete. That is, if an entity bills the 4-digit code from the list instead of the 5-digit code, the claim will be returned to the laboratory. However, if the laboratory bills the appropriate 5-digit code, the claim will not be paid, as the 5-digit code is not on the covered code list. Other errors include instances in which the code and the descriptor did not match.

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/ncd/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

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

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 Register**s.

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.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals, and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this proposed notice would not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis *if a rule may have* a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this proposed notice would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This proposed notice would have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet *when it promulgates a proposed rule (and subsequent final rule)* that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed notice and have determined that it would not have a substantial effect on State or local governments.

In accordance with the provisions of Executive Order 12866, this document was reviewed by the Office of Management and Budget.

Authority: Sections 1816(a), 1833, 1842(a), 1861, 1862(a)(1)(A), and 1862(a)(7) of the Social Security Act (42 U.S.C. 1395h(a), 1395l, 1395u(a), 1395x, 1395y(a)(1)(A), and 1395y(a)(7))

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 23, 2003.

Thomas A Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: September 16, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–31573 Filed 12–23–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1226–GNC]

RIN 0938–ZA44

Medicare Program; Criteria and Standards for Evaluating Intermediary, Carrier, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carrier Performance During Fiscal Year 2004

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

ACTION: General notice with comment period.

SUMMARY: This notice describes the criteria and standards to be used for evaluating the performance of fiscal intermediaries, carriers, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) regional carriers in the administration of the Medicare program beginning on the first day of the first month following publication of this notice in the **Federal Register**. The results of these evaluations are considered whenever we enter into, renew, or terminate an intermediary agreement, carrier contract, or DMEPOS regional carrier contract or take other contract actions, for example, assigning or reassigning providers or services to an intermediary or designating regional or national intermediaries. We are requesting public comment on these criteria and standards.

DATES: *Effective Date:* The criteria and standards are effective January 2, 2004.

Comment Period: Comments will be considered if we receive them at the appropriate address as provided below no later than 5 p.m. (EDT) on January 23, 2004.

ADDRESSES: In commenting, please refer to file code CMS–1226–GNC. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission. Mail written comments (one original and two copies) to the following address:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1226–GNC, PO Box 8016, Baltimore, MD 21244–8016.

If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, 20201 or Room C5–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Sue Lathroum, (410) 786–7409.

SUPPLEMENTARY INFORMATION: In several instances, we identify a Medicare manual as a source of more detailed requirements. Medicare fee-for-service contractors have copies of the various Medicare manuals referenced in this notice. Members of the public also have access to our manual instructions.

Medicare manuals are available for review at local Federal Depository Libraries (FDLs). Under the FDL Program, government publications are sent to approximately 1,400 designated public libraries throughout the United States. To locate the nearest FDL, individuals should contact any public library.

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of nearly every Federal government publication, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. Information may also be obtained from the following Web site: *http://www.cms.hhs.gov/manuals.*

Finally, all of our regional offices (ROs) maintain all Medicare manuals for