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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3119-FN]

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: Final notice.

SUMMARY: This notice finalizes the procedures proposed in the **Federal Register** on December 24, 2003 (68 FR 74607). It establishes the procedures for maintaining the lists of codes that were included in the national coverage determinations (NCDs) that were announced in an addendum to the final rule published in the **Federal Register** on November 23, 2001 (66 FR 58788). The final notice also sets forth the circumstances in which a laboratory is permitted to use the date a specimen was retrieved from storage for testing as the date of service instead of the date of collection.

DATES: *Effective Date:* The notice is effective on March 28, 2005.

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

SUPPLEMENTARY INFORMATION:

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. 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 seeking payment under the Medicare and Medicaid programs.

Under section 1842(a) of the Act, we contract with carriers to perform bill processing and benefit payment functions for Medicare Part B (Supplementary Medical Insurance). 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, like 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. If a contractor develops a local coverage determination (LCD) (formerly called local medical review policies (LMRP)), its LCD/LMRP applies only within the geographic area it serves as stated in the September 26, 2003 notice (68 FR 55636). Current guidance regarding the development of LCDs/LMRPs appears in section 13.1.3 of the Program Integrity Manual (HCFA Pub. 100-8).

B. Legislation

Section 4554(b)(1) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-133) enacted on August 5, 1997, mandates the 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 for 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 in the **Federal Register** (65 FR 13082) proposing to adopt the committee's recommendations. The final rule was published on November

23, 2001 in the **Federal Register** (66 FR 58788).

C. National Coverage Determinations (NCDs)

The final rule on coverage and administrative policies for clinical diagnostic laboratory services includes an addendum containing NCDs for 23 clinical diagnostic laboratory tests. These NCDs are binding on all Medicare carriers, intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans.

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 or 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.

On April 27, 1999, we published a notice (64 FR 22619) outlining our procedures for developing and revisiting NCDs. 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 will use the NCD process for making changes to the laboratory NCDs. At the conclusion of the NCD decision-making process, decision memoranda will be published on the CMS Web site 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>.

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. Since 1989, § 424.32(a)(2) has required the reporting of ICD-9-CM coding on all bills for physicians' 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 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 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 but in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) may be issued semi-annually beginning on October 1, 2004. Updated ICD-9-CM codes can be found at <http://cms.hhs.gov/paymentsystems/icd9>. 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 (PPS). Section 503(a) of the MMA requires updating of the ICD-9-CM codes in April of each year, but the

addition of these codes will not require adjustment to the payment systems until the following fiscal year. Consequently, if we update codes for April, we will do so through our issuance system and follow it up with a notice in the subsequent PPS Final Rule in the **Federal Register**. These codes are not accompanied with payment adjustments. 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.

The American Medical Association (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. 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>.

E. Implementation of NCDs

One of the goals of section 4554 of the BBA is to promote uniformity in Medicare processing of claims for clinical diagnostic laboratory services. We developed an electronic edit table module that is installed in each of the Medicare claims processing contractors' systems. The edit module ensures 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 will have implemented the laboratory NCDs at the same time. The edit module is updated quarterly as necessary to accommodate coding changes and NCD modifications.

II. Provisions of the Proposed Notice

A. Proposed Process for Code Maintenance

In the preamble of the final rule published on November 23, 2001 in the **Federal Register** (66 FR 58788), we announced that we intend 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 a notice published on September 26, 2003 (68 FR 55634). These notices describe an evidence-based method in which determinations are made based on the scientific literature. Formal requests for an NCD must be made in accordance with the provisions of the September 26, 2003 notice (68 FR 55636). The NCD process is further modified by the provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We expect to issue a guidance document incorporating the changes made to the NCD process by section 731 of the MMA in the near future. A summary of the NCD process is posted on the Internet at <http://www.cms.hhs.gov/coverage/8a4.asp>.

We 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 requests for other changes to the existing laboratory NCD code lists.

We proposed to establish three separate processes for requesting changes to the laboratory NCDs. In this final notice, we are finalizing the procedures we proposed in the December 24, 2003 **Federal Register** (68 FR 74607). Substantive changes would use the normal evidence-based NCD process. Coding changes that flow from the existing NCD narratives of covered indications would be requested by a letter detailing how the covered indication(s) in the narrative support the proposed coding and descriptor changes. Scientific evidence in support of these requests would not be required but would be welcomed to support the requestor's position. Typographical errors and new codes and descriptors would be implemented through program instructions without public comments.

1. Codes that Flow From the Covered Indications Narrative

We proposed to establish an abbreviated process for handling requests for certain NCD narrative based coding changes to the laboratory NCDs. In order for change requests to qualify for this process, the new coding must flow from the existing narrative indications in a laboratory NCD. Requests that, in effect, constitute requests to add new indications must continue to use the NCD evidence-based process outlined in the September 26, 2003 **Federal Register** (68 FR 55636).

The abbreviated process is similar to the NCD process in that it includes

posting on the Internet and an opportunity for the public to comment before coding change(s) are made. The principal difference between the processes is the volume of information required. Requesters using the abbreviated process will submit a letter detailing the provision of the NCD narrative that clearly indicates coverage for the requested code. Scientific literature in support of the coding change is not required. However, scientific literature supporting the request and clinical guidelines from relevant healthcare organizations is welcome.

2. Clerical Coding Change

The ICD-9-CM diagnosis codes and the CPT procedure codes are periodically updated with coding and descriptor changes. Codes and descriptors that are changed through this process may include those that have been incorporated in the laboratory NCDs. We believe the NCDs must be updated quickly to reflect current coding practices whenever the coding and descriptor changes occur. Similarly, clerical errors in laboratory NCD code lists, like typographical errors, should be corrected as quickly as possible. Consequently, we proposed to establish a streamlined process for making clerical changes to codes contained within the laboratory NCDs. (See the December 24, 2003 **Federal Register** notice (68 FR 74607)).

Under this proposal, the general public would 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 would initiate this process to correct clerical and ministerial errors 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>.

In summary, we proposed to establish three separate processes for maintaining the laboratory NCDs. We would make clerical and ministerial changes quickly without prior posting on the Internet or public comment. We would announce clerical changes 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 the submission of 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 continue to be handled through the normal NCD process described in the September 26, 2003 **Federal Register** (68 FR 55634). Requests for substantive changes to NCDs would continue to require scientific evidence in support of the change in policy. We would post a tracking sheet announcing our acceptance of a request to substantively change an NCD on the Internet and public comments would be solicited for 30 days before making a determination. The draft decision memorandum for NCDs would be open to public comment before implementation.

B. Publication of the Code Lists for the Laboratory NCDs

We have generally published NCDs in the Medicare Coverage Issues Manual (CIM). This manual was replaced by the National Coverage Determination (NCD) Manual.

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

C. Date of Service

In the final rule of coverage and administrative policies for clinical diagnostic laboratory services that we published on November 23, 2001 (66 FR 58792), we clarified the date of service for clinical diagnostic laboratory services. 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 proposed to further clarify the date of service provision for clinical diagnostic laboratory services. We suggested requiring 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.

We have received several comments since issuing the final rule that stated that the common practice in the laboratory community is to use the date the collection ended as the date of service. We proposed to alter our policy to specify that the date of service would be the date the collection ended instead of the date the collection began.

III. Analysis of and Responses to Public Comments

We received no public comments on the December 24, 2003 proposed notice (68 FR 74607).

IV. Provisions of the Final Notice

We are establishing the provisions of the proposed notice as final.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-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 OMB should approve an information collection, section 3506(c)(2)(A) of the PRA requires that we solicit comment 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 to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In summary, we are establishing 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 that the codes

flow from the existing narrative indications for the clinical diagnostic laboratory test. In other words, the requested change must be classified as a correction, an updating change, or a 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 issues of the **Federal Register**.

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.

However, based on the current number of submissions received on an annual basis (less than 10), this is not an information collection defined by the PRA (5 CFR 1320.3(c)(4)). If in the future we receive more than 10 responses on an annual basis, we will submit these information collection requirements to OMB for review and approval as required by the PRA.

VI. Regulatory Impact Statement

In this notice, we establish an abbreviated mechanism for making changes to the lists of ICD-9-CM and CPT codes that are included in the laboratory NCDs. We clarify 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 rule to impose any significant burden on laboratories. The established 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 final notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 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 alternatives 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 final 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 notice is purely procedural and, therefore, is not expected to impose any appreciable burden or generate compliance costs for laboratories.

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. For purposes of the RFA, approximately 80 percent of clinical diagnostic laboratories are considered small businesses according to the Small Business Administration's size standards with total revenues of \$29 million or less 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 final notice will 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 604 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 final notice will 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 notice 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 final notice will 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 final

notice that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final notice and have determined that it will not have a substantial effect on State or local governments.

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

Dated: September 1, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 9, 2004.

Tommy G. Thompson,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1219-N]

RIN 0938-AL76

Medicare Program; Changes in Geographical Boundaries of Durable Medical Equipment Regional Service Areas

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

ACTION: Notice.

SUMMARY: This notice announces changes to the geographical boundaries of the four Durable Medical Equipment (DME) service areas applicable to future awards of the Medicare Administrative Contracts (MACs). We identify which States and territories are assigned to each of the four DME service areas, and include the factors and criteria that we used to change the geographical boundaries.

DATES: *Effective Date:* This notice is effective on March 28, 2005.

Applicability Date: On March 28, 2005, the new geographical boundaries will apply to DME MACs and not current DME regional carrier contracts.

FOR FURTHER INFORMATION CONTACT: Pat Williams, (410) 786-6139.

SUPPLEMENTARY INFORMATION:

I. Background

Medicare has covered medically necessary items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) under Part B since the inception of the program in 1966. In