

FOR FURTHER INFORMATION CONTACT:
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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