CHAPTER 61

INDEPENDENT CLINICAL LABORATORIES

Authority

N.J.S.A. 30:4D-1 et seq. and 30:4J-8 et seq.

Source and Effective Date

R.2006 d.244, effective June 7, 2006.
See: 38 N.J.R. 1383(a), 38 N.J.R. 2827(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 61, Independent Clinical Laboratories, expires on December 4, 2013. See: 45 N.J.R. 2089(a).

Chapter Historical Note

Chapter 61, Independent Laboratory Services, was adopted as R.1971 d.57, effective April 21, 1971. See: 3 N.J.R. 43(a), 3 N.J.R. 83(b).

Subchapter 3, Laboratory Code List, was repealed and a new Subchapter 3, HCFA Common Procedure Coding System (HCPCS), was adopted effective March 3, 1986, as R.1986 d.52. See: 17 N.J.R. 1519(b), 18 N.J.R. 478(a).

Pursuant to Executive Order No. 66(1978), Chapter 61, Independent Laboratory Services, was readopted as R.1991 d.138, effective February 15, 1991. See: 22 N.J.R. 3713(a), 23 N.J.R. 838(e).

Chapter 61, Independent Laboratory Services, was repealed, and Chapter 61, Independent Clinical Laboratories, was adopted as new rules by R.1996 d.68, effective February 5, 1996. See: 27 N.J.R. 4861(a), 28 N.J.R. 1054(a).

Pursuant to Executive Order No. 66(1978), Chapter 61, Independent Clinical Laboratories, was readopted as R.2001 d.79, effective February 1, 2001. See: 32 N.J.R. 4167(a), 33 N.J.R. 781(c).

Subchapter 3, HCFA Common Procedure Coding System (HCPCS), was renamed Healthcare Common Procedure Coding System (HCPCS) by R.2006 d.37, effective January 17, 2006. See: 37 N.J.R. 3182(a), 38 N.J.R. 807(a).

Chapter 61, Independent Clinical Laboratories, was readopted as R.2006 d.244, effective June 7, 2006. See: Source and Effective Date. See, also, section annotations.

In accordance with N.J.S.A. 52:14B-5.1b, Chapter 61, Independent Clinical Laboratories, was scheduled to expire on June 7, 2013. See: 43 N.J.R. 1203(a).

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SUBCHAPTER 1. GENERAL PROVISIONS

10:61-1.1 Purpose and scope

This chapter outlines the policies and procedures for coverage of clinical laboratory services that must be met in order to qualify for reimbursement under the Medicaid/NJ FamilyCare fee-for-service programs. The services of a qualified clinical laboratory for which reimbursement may be made relate only to diagnostic tests performed in a laboratory which is independent of a physician's office, a participating hospital, or other facility. Rules for laboratory services provided by other types of providers are included in the Medicaid/NJ FamilyCare rules for those particular providers. Diagnostic laboratory tests, for purposes of this chapter, do not include diagnostic radiological studies.

Amended by R.2006 d.37, effective January 17, 2006.
See: 37 N.J.R. 3182(a), 38 N.J.R. 807(a).
Deleted "New Jersey" preceding "Medicaid"; added "NJ FamilyCare fee-for-service" and "NJ FamilyCare."

10:61-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Automated multichannel tests" means laboratory tests which can be and are frequently performed as groups and combinations (profiles) on automated multichannel equipment.

"CLIA" means the Clinical Laboratory Improvement Amendments of 1988, which extends the scope of Federal governmental regulation of laboratories to all laboratory sites where laboratory tests are performed, including physicians' offices. The purpose of this legislation is to uniformly ensure the quality and reliability of medical tests performed by all laboratories that test human specimens.

"CLIA Identification Number" means a 10 digit identification number issued by the Centers for Medicare & Medicaid Services (CMS) to independent clinical laboratories and other entities which perform laboratory testing. A CLIA Identification Number must be on file with the New Jersey Medicaid/NJ FamilyCare program before payment is made for any laboratory testing.

"Clinical laboratory services" means professional and technical laboratory services provided by an independent clinical laboratory when ordered by a physician or other licensed practitioner of the healing arts within the scope of his or her practice as defined by the laws of the state in which he or she practices.

"Panel" means laboratory tests that are associated with organ or disease oriented areas, such as organ "panels" (for example, hepatic function panel). The tests listed with each panel identify the defined components of that panel.

"Profile" means a combination of laboratory tests that can be and are frequently done as groups and in combinations on automated multi-channel equipment (for example, SMA6, SMA).

"Reference laboratory" means a laboratory meeting the requirements stipulated in N.J.A.C. 10:61-1.4 which performs specific tests at the request of another approved certified laboratory.

"Service laboratory" means a laboratory meeting the requirements stipulated in N.J.A.C. 10:61-1.4 which performs specific tests on the laboratory's own premises.

Amended by R.2006 d.37, effective January 17, 2006.
See: 37 N.J.R. 3182(a), 38 N.J.R. 807(a).
Rewrote definition "CLIA Identification Number".

10:61-1.3 Scope of services

Each laboratory shall provide the New Jersey Health Services Program, Office of Utilization Management, Mail Code #33, PO Box 712, Trenton, New Jersey 08625-0712, with a listing of tests, including panels and profiles actually performed on its premises (address to be identified) and a current lab price list, including discounts, with an update of said list on a semiannual basis; beginning with the first listing due six months from the date of the last report filed by providers enrolled as of January 17, 2006.

Amended by R.2001 d.79, effective March 5, 2001.
See: 32 N.J.R. 4167(a), 33 N.J.R. 781(c).
Amended by R.2006 d.37, effective January 17, 2006.
See: 37 N.J.R. 3182(a), 38 N.J.R. 807(a).
Rewrote the section.

10:61-1.4 Requirements for provider participation; general

(a) To qualify for participation as a clinical laboratory under the Medicaid/NJ Family Care program, the following requirements must be met:

1. Licensure and/or approval by the New Jersey State Department of Health or comparable agency in the state in which the facility is located. This includes meeting certificate of need and licensure requirements, when required, and all applicable laboratory provisions of the New Jersey State Sanitary Code (see N.J.A.C. 8:45);

2. Enrollment as an independent laboratory under the Title XVIII Medicare program (see 42 CFR 493.1);

3. Meet the requirements of an independent clinical laboratory under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (see 42 USC 1396(a)(9)). (See N.J.A.C. 10:61-2.1(a)5.)

(b) In order to participate in the Medicaid/NJ FamilyCare program as an independent laboratory provider, the following documents shall be submitted to Unisys Corporation, Provider Enrollment, PO Box 4804, Trenton, N.J. 08650-4804:

1. Form FD-20, Medicaid Provider Application Form;

2. Form FD-62, Medicaid Provider Agreement;

3. A copy of CMS 1513, Disclosure of Ownership, Control and Interest Statement;

4. A copy of the Medicare certification; and

5. A copy of the documents to certify the lab meets the CLIA requirements.

(c) The provider will be notified by Unisys as to whether their application for participation was approved or disapproved by the Medicaid/NJ FamilyCare Program.

Amended by R.2006 d.37, effective January 17, 2006.
See: 37 N.J.R. 3182(a), 38 N.J.R. 807(a).
Added "NJ FamilyCare" following "Medicaid/" throughout; in introductory paragraphs (a) and (c), deleted "New Jersey" preceding "Medicaid"; in (b)3, substituted "CMS" for "HCFA".

10:61-1.5 Medicare-Medicaid relationship

(a) Upon approval as an independent laboratory provider for Title XIX Medicaid participation and reimbursement, the requirements for independent laboratory services under the Title XVIII Medicare program shall be followed.

(b) A laboratory approved for Medicaid/NJ FamilyCare participation shall only provide services and be reimbursed for the specialties and subspecialties specifically approved for Medicare participation.

(c) State, county and municipal laboratories located in New Jersey may qualify for Medicaid/NJ FamilyCare reimbursement provided they meet the criteria in N.J.A.C. 10:61-1.4 and 1.5.

(d) Any entity that performs diagnostic tests in connection with its provider practice shall comply with this chapter and shall have a CLIA Identification Number to perform clinical laboratory testing reimbursable by the Medicaid/NJ FamilyCare program. A CLIA Identification Number must be on file with the Medicaid/NJ FamilyCare program before payment is made for any laboratory testing.

Amended by R.2006 d.37, effective January 17, 2006.
See: 37 N.J.R. 3182(a), 38 N.J.R. 807(a).
Added "NJ FamilyCare" following "Medicaid/" throughout; in (d), deleted "New Jersey" preceding "Medicaid" throughout and deleted reference to N.J.A.C. 10:49-24.