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

Chapter 61, Independent Clinical Laboratories, expires on June 7, 2011.

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Subchapter 3, Laboratory Code List, was repealed and a new Subchapter 3, HCFA Common Procedure Coding System (HCPCS), was adopted effective March 3, 1986, as R.1986 d.52.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Chapter 61, Independent Laboratory Services, was repealed, and Chapter 61, Independent Clinical Laboratories, was adopted as new rules by R.1996 d.68, effective February 5, 1996.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 by R.2006 d.244, effective June 7, 2006. See: Source and Effective Date. See, also, section annotations.

CHAPTER TABLE OF CONTENTS

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.

10:61-1.6 Recordkeeping

(a) All requests for clinical laboratory services shall require an explicit order personally signed by the physician or other licensed practitioner requesting the services. The written order shall contain the specific test requested, and shall be on file with the billing laboratory and available for review by Medicaid/NJ FamilyCare representatives, along with the results of the tests billed.

(b) The written order shall contain the specific clinical laboratory test(s) requested and shall be supported by documentation in the referring physician's/practitioner's medical records.

(c) Standing orders shall be:

1. Patient specific, and not blanket requests from the physician or licensed practitioner;

2. Medically necessary and related to the diagnosis of the recipient; and

3. Effective for no longer than a 12 month period from the date of the physician's/practitioner's signature.

(d) Telephone laboratory orders shall be followed up with a written request and shall be on file with the clinical laboratory.

(e) The results of the tests billed shall be on file with the billing laboratory performing tests. The results shall be available for review by Medicaid/NJ FamilyCare representatives.

(f) The Medicaid/NJ FamilyCare program shall have the right to inspect all records, files and documents of in-State and out-of-State service and reference clinical laboratories which provide laboratory tests and services for Medicaid/NJ FamilyCare beneficiaries.

Amended by R.2006 d.37, effective January 17, 2006.
See: 37 N.J.R. 3182(a), 38 N.J.R. 807(a).
In (a), (e) and (f), added "NJ FamilyCare" following "Medicaid/" throughout; in (f), deleted "New Jersey" preceding "Medicaid" throughout, substituted "Program" for "program" and "beneficiaries" for "recipients".

10:61-1.7 Basis of reimbursement

Reimbursement shall be on the basis of the lowest professional charge, not to exceed an allowance determined reasonable by the Commissioner of Human Services, and further limited by Federal policy relative to payment of clinical laboratory services. The maximum fee schedule (allowance) is set forth at N.J.A.C. 10:61-3. In no event shall the charge to the Medicaid/NJ FamilyCare program exceed the provider's charge for identical services to other groups or individuals.

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/" and deleted "New Jersey" preceding "Medicaid".

SUBCHAPTER 2. PROVISION OF SERVICE

10:61-2.1 Clinical Laboratory Improvement Amendments (CLIA) requirements

(a) All independent clinical laboratories and other entities providing clinical laboratory services to Medicaid/NJ FamilyCare beneficiaries must meet the requirements of the Clinical Laboratory Improvement Amendments (CLIA) of 1988. These requirements include that the provider must have one of the following:

1. A certificate of waiver;

2. A certificate of compliance;

3. A registration certificate;

4. A certificate for provider-performed microscopy (PPM) procedures;

5. A certificate of accreditation, and a registration certificate or a certificate of compliance; or

6. Be deemed CLIA exempt due to accreditation by a private, nonprofit accreditation organization or exempted under an approved state laboratory program. (See code of Federal Regulations 42 CFR 493)

Amended by R.2006 d.37, effective January 17, 2006.
See: 37 N.J.R. 3182(a), 38 N.J.R. 807(a).
In introductory paragraph (a), added "NJ FamilyCare" following "Medicaid/".

10:61-2.2 Specific services

(a) The sum of any number of the components of a battery of tests shall not exceed the total charged for the group offering (panel or profile), whether done by automation or bench testing, whether or not the equipment is available in the facility. A battery of tests is considered to be those components of a panel or series of tests which, when combined, mathematically or otherwise, comprise a finished identifiable laboratory study or studies. Examples are:

1. The components of a metabolic profile or other automated laboratory study;

2. An MCH, MCV, or other test, as a component of a C.B.C.;

3. Inclusive of all ova and parasites in a stool examination.

(b) If the components of a profile or panel are billed separately, total reimbursement for the components of the panel or profile shall not exceed the Medicaid/NJ FamilyCare fee allowance for the panel or profile itself.

(c) In no instance shall reimbursement exceed the Medicare Fee Schedule.

(d) Where tests are referred by an approved service laboratory to an approved reference laboratory, the approved

reference laboratory shall be a Medicaid/NJ FamilyCare provider and shall directly bill the Medicaid/NJ FamilyCare program for the service.

1. The initiating laboratory shall only refer clinical laboratory tests to laboratories which have a valid CLIA Identification Number and are Medicaid/NJ FamilyCare approved providers.

(e) The policy on reimbursement for visits to the nursing home, residential health care facility, or to the beneficiary's home by an independent lab for the purposes of obtaining blood by venous or arterial puncture is as follows:

1. Utilize HCPCS code W8900 for visits to homebound beneficiaries in their own home or living in a residential health care facility, group home, or boarding home. This code may be used only once per trip regardless of the number of patients seen and requires a distance in excess of 20 miles per round trip.

2. Utilize HCPCS code 36415 for a visit to a beneficiary in a nursing facility, or Intermediate Care Facility/ Mental Retardation (ICF/MR).

3. Reimbursement will not be made for travel to other sites including, but not limited to, hospitals, physician offices, or clinics.

Amended by R.2001 d.79, effective March 5, 2001.
See: 32 N.J.R. 4167(a), 33 N.J.R. 781(c).
In (a)1, substituted "metabolic" for "chemistry".
Amended by R.2006 d.37, effective January 17, 2006.
See: 37 N.J.R. 3182(a), 38 N.J.R. 807(a).
In introductory paragraph (a), deleted "Where batteries constitute a profile, they shall be billed in that manner." and substituted "panel" for "test"; in (b) and introductory paragraph (d), added "NJ FamilyCare" following "Medicaid/" throughout; in (b), added "panel or" preceding "profile"; in (d)1, deleted "New Jersey"; and rewrote (e)2.

10:61-2.3 Limitations on laboratory services

(a) Tests performed by a non-approved laboratory are not reimbursable. The referring laboratory shall verify approved status.

(b) Additional payment will not be made to a laboratory for obtaining specimens, except when performed in a long-term care facility, boarding home, or home.

(c) A laboratory shall be reimbursed only those tests that are within the specialty/subspecialty categories indicated in its CLIA approval.

(d) Laboratory services provided primarily for the diagnosis or treatment of infertility shall not be covered by the Medicaid/NJ FamilyCare program.

1. For those HCPCS procedure codes which are determined to be primarily for the diagnosis of infertility, refer to the HCPCS subchapter and the Indicator "F."

Amended by R.2006 d.37, effective January 17, 2006.
See: 37 N.J.R. 3182(a), 38 N.J.R. 807(a).
In (d), added "NJ FamilyCare" following "Medicaid/" and deleted "New Jersey".

10:61-2.4 Laboratory rebates

Rebates by reference laboratories, service laboratories, physicians or other utilizers or providers of laboratory service are prohibited under the Medicaid/NJ FamilyCare program. Rebates shall include refunds, discounts or kickbacks, whether in the form of money, supplies, equipment, or other things of value. Laboratories shall not rent space or provide personnel or other considerations to a physician or other practitioner, whether or not a rebate is involved.

Amended by R.2006 d.37, effective January 17, 2006.
See: 37 N.J.R. 3182(a), 38 N.J.R. 807(a).
Deleted designation "(a)" and added "NJ FamilyCare" following "Medicaid/".

SUBCHAPTER 3. HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS)

10:61-3.1 Purpose, scope and general provisions

(a) The Medicaid/NJ FamilyCare program uses the Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS), for 2006, established and maintained by CMS in accordance with the Health Insurance Portability and Accountability Act, of 1996, 42 U.S.C. §§1320d et seq., and the American Medical Association (AMA) Current Procedural Terminology (CPT) codes published by PMIC, 4727 Wilshire Blvd., Suite 300, Los Angeles, CA 90010. The HCPCS and CPT codes are incorporated herein by reference, as amended and supplemented. AMA and CMS revisions to the CPT codes and the Healthcare Common Procedure Coding System (code additions, code deletions and replacement codes) will be reflected in this chapter through publication of a notice of administrative change in the New Jersey Register. Revisions to existing and new reimbursement amounts codes specified by the Department and specification of new reimbursement amounts for new codes will be made through rulemaking in accordance with the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. HCPCS follows the American Medical Association's Physicians' Current Procedural Terminology (CPT) (American Medical Association, P.O. Box 10950, Chicago, IL 60610.) architecture, employing a five-position code and as many as two two-position modifiers. Unlike the CPT numeric design, the CMS-assigned codes and modifiers contain alphabetic characters.

(b) HCPCS has been developed as a three-level coding system. The CPT procedure narratives for Level I codes are incorporated herein by reference.

1. Level 1 codes (Narratives found in CPT). CPT is a listing of descriptive terms and numeric identifying codes and modifiers for reporting medical services and procedures performed by physicians. (See N.J.A.C. 10:61-3.2.)