

CHAPTER 61**INDEPENDENT CLINICAL LABORATORIES****Authority**

N.J.S.A. 30:4D-6b(17); 30:4D-7, 7a, b, and c; and 30:4D-12.

Source and Effective Date

R.2001 d.79, effective February 1, 2001.
See: 32 N.J.R. 4167(a), 33 N.J.R. 781(c).

Chapter Expiration Date

Chapter 61, Independent Clinical Laboratories, expires on February 1, 2006.

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Subchapter 3, Laboratory Code List, was repealed and a new Subchapter 3, HCFA Common Procedure Coding System (HCPCS), was adopted effective March 3, 1986, as R.1986 d.52.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Chapter 61, Independent Laboratory Services, was repealed, and Chapter 61, Independent Clinical Laboratories, was adopted as new rules by R.1996 d.68, effective February 5, 1996.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

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).

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APPENDIX A**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.

HCPCS				HCPCS			
IND	Code	MOD	Maximum Fee Allowance \$	IND	Code	MOD	Maximum Fee Allowance \$
	87300		6.00		87515		25.00
	87301		12.00		87516		38.00
	87320		12.50		87517		20.00
	87320	FP	12.50		87520		25.00
	87320	WF	12.50		87521		38.00
	87324		12.50		87522		20.00
	87327		12.18		87525		25.00
	87328		12.50		87526		38.00
	87329		12.00		87527		20.00
	87332		12.00		87528		25.00
	87335		12.00		87529		38.00
	87336		12.18		87530		20.00
	87337		12.18		87531		25.00
	87338		9.00		87532		38.00
	87339		12.18		87533		20.00
	87339	QW	12.18		87534		25.00
	87340		14.00		87535		38.00
	87340	UD	14.00		87536		117.00
	87341		11.42		87537		25.00
	87350		14.00		87538		38.00
	87380		20.00		87539		20.00
	87385		15.00		87540		25.00
	87390		15.00		87541		38.00
	87391		15.00		87542		20.00
	87400		6.00		87550		25.00
	87420		12.00		87551		38.00
	87425		12.00		87552		20.00
	87427		12.18		87555		25.00
	87430		12.00		87556		38.00
	87449	QW	12.00		87557		20.00
	87449		12.00		87560		25.00
	87450		10.00		87561		38.00
	87451		10.60		87562		20.00
	87470		20.00		87580		25.00
	87471		30.00		87581		38.00
	87472		20.00		87582		20.00
	87475		25.00		87590		25.00
	87476		38.00		87590	FP	25.00
	87477		20.00		87591		38.00
	87480		25.00		87591	FP	38.00
	87481		38.00		87592		20.00
	87482		20.00		87620		25.00
	87485		25.00		87620	FP	25.00
	87486		38.00		87621		38.00
	87487		20.00		87621	FP	38.00
	87490		20.00		87622		20.00
	87490	FP	20.00		87650		25.00
	87491		38.00		87651		38.00
	87491	FP	38.00		87652		20.00
	87492		20.00		87660		25.00
	87495		25.00		87797		25.00
	87496		38.00		87798		38.00
	87497		20.00		87799		20.00
	87510		25.00		87800		25.00
	87511		38.00		87801		38.00
	87512		20.00		87802		12.17

HCPCS				HCPCS			
IND	Code	MOD	Maximum Fee Allowance \$	IND	Code	MOD	Maximum Fee Allowance \$
	87803		12.17		88161		12.00
	87804		12.17		88161	26	7.00
	87804	QW	12.17		88161	TC	5.00
	87807		12.17		88162		59.00
	87810		12.00		88162	26	43.00
	87850		12.00		88162	TC	16.00
	87880		12.00		88164		6.00
	87880	QW	12.00		88164	FP	6.00
	87899		12.00		88165		6.00
	87899	QW	12.00		88165	FP	6.00
N	87901		350.00		88166		6.00
N	87903		675.72		88166	FP	6.00
N+	87904		36.00		88167		6.00
	87999		B.R.		88167	FP	6.00
	88104		12.00		88172		40.00
	88104	26	7.00		88172	26	28.00
	88104	TC	5.00		88172	TC	12.00
	88104		12.00		88173		25.00
	88106		812.00		88173	26	20.00
	88106	26	7.00		88173	TC	5.00
	88106	TC	5.00		88174		23.50
	88107		12.00		88175		28.50
	88107	26	7.00		88182		64.11
	88107	TC	5.00		88182	TC	19.07
	88108		12.00		88182	26	45.05
	88108	26	7.00		88184		26.60
	88108	TC	5.00		88185		26.60
	88112		18.00		88187		12.00
	88125		7.00		88188		12.00
	88125	26	6.00		88189		12.00
	88125	TC	1.00		88199		B.R.
	88130		9.65		88230		90.00
	88130	26	7.00		88233		90.00
	88140		4.20		88235		90.00
	88140	26	3.00		88237		90.00
	88141	FP	6.00		88239		90.00
	88141		6.00		88240		7.75
	88142		18.00		88241		7.75
	88142	FP	18.00		88245		184.00
	88143	FP	18.00		88248		230.00
	88147		13.48		88249		230.00
	88147	FP	13.48		88262		172.00
	88148		13.48		88263		184.00
	88148	FP	13.48		88264		172.00
	88150		6.00		88267		230.00
	88150	FP	6.00		88271		16.00
	88152		6.00		88273		35.00
	88152	FP	6.00		88274		45.00
	88153		6.00		88275		55.00
	88153	FP	6.00		88280		34.00
	88154		6.00		88283		46.00
	88154	FP	6.00		88285		27.23
N	88155		6.00		88289		40.00
	88160		7.00		88291		26.82
	88160	26	5.00		88299		B.R.
	88160	TC	2.00		88300		9.35

HCPCS				HCPCS			
IND	Code	MOD	Maximum Fee Allowance \$	IND	Code	MOD	Maximum Fee Allowance \$
	88300	26	6.55		88347	TC	10.00
	88300	TC	2.80	N	88348		141.81
	88300	UD	9.35		88348	26	98.22
	88300	UD 26	6.55		88348	TC	46.59
	88302		20.85	N	88349		88.70
	88302	26	10.80		88349	26	56.06
	88302	TC	10.05		88349	TC	32.63
	88304		26.00		88355		126.00
	88304	26	16.67		88355	26	94.50
	88304	TC	9.33		88355	TC	31.50
	88304	UD	26.00		88356		126.00
	88304	UD 26	19.00		88356	26	94.50
	88305		40.00		88356	TC	31.50
	88305	26	30.00		88358		94.50
	88305	FP	40.00		88358	26	63.00
	88305	TC	10.00		88358	TC	31.50
	88307		59.00		88360		94.00
	88307	26	44.00		88362		126.00
	88307	TC	15.00		88362	26	94.50
	88309		89.00		88362	TC	31.50
	88309	26	66.00		88365		47.25
	88309	TC	23.00		88365	26	31.50
	88311		6.00		88365	TC	15.75
	88311	26	4.00		88367		47.25
	88311	TC	2.00		88368		47.25
	88312		13.00		88371		30.00
	88312	26	9.00		88371	26	15.00
	88312	TC	4.00		88372		31.00
	88313		10.00		88372	26	15.00
	88313	26	6.00		88399		B.R.
	88313	TC	4.00		88400		3.00
	88314		12.00		89050		.90
	88318		8.00		89051		.90
	88319		8.00		89055		4.76
	88319	26	5.00		89060		8.50
	88319	TC	3.00		89100		20.00
	88321		28.00		89105		6.00
	88323	26	19.00		89125		.60
	88323	TC	14.00		89130		6.00
	88323		33.00		89132		6.00
	88325		44.00		89135		6.00
	88329		33.00		89136		6.00
	88331		48.00		89140		12.00
	88331	26	41.00		89141		12.00
	88331	TC	7.00		89160		2.10
	88332		15.00		89190		2.20
	88332	26	10.00		89205		1.20
	88332	TC	5.00		89220		8.00
	88342		9.00		89225		4.50
	88342	26	7.00		89230		9.00
	88342	TC	2.00		89310		4.80
	88346		40.00		89320		9.00
	88346	26	30.00		89321		9.00
	88346	TC	10.00		89325		13.00
	88347		45.00		93000		16.00
	88347	26	35.00		93012		11.00

IND	HCPCS Code	MOD	Maximum Fee Allowance \$
	93040		10.00
	93041		6.00
	95070		18.00
	95071		18.00
	95075		18.00
	95165		4.50

Amended by R.2001 d.79, effective March 5, 2001.
 See: 32 N.J.R. 4167(a), 33 N.J.R. 781(c).
 Rewrote the section.
 Amended by R.2002 d.323, effective October 7, 2002.
 See: 34 N.J.R. 959(a), 34 N.J.R. 3524(a).
 In HCPCS Code 82731, increased the Total Fee from 6.60 to 71.20.
 Amended by R.2003 d.15, effective January 6, 2003.
 See: 34 N.J.R. 2676(a), 35 N.J.R. 230(c).
 Updated the table of HCPCS procedure codes.
 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.

10:61-3.3 HCPCS procedure codes, procedure description and maximum fee allowance schedule for Level 2

IND	HCPCS Code	MOD	Procedure Description	Maximum Fee Allowance
	G0015		Telephonic or telemetric transmission	\$11.00
	G0027		Semen analysis	2.40
	G0141		Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician	10.00
	G0306		Complete CBC, automated (HGB, HCT, RBC, WBC, without platelet count) and automated WBC differential count	5.00
	G0307		Complete CBC, automated (HGB, HCT, RBC, WBC, without platelet count)	4.80
	G0328		Immunoassay infectious agent, qualitative, fecal	7.00
	G0328	QW	Immunoassay infectious agent, qualitative, fecal	7.00
	P3000		Screening papanicolaou smear, cervical or vaginal, up to three smears; by technician under physician supervision	6.00
	P3001		Screening papanicolaou smear, cervical or vaginal, requiring interpretation by a physician	6.00

IND	HCPCS Code	MOD	Procedure Description	Maximum Fee Allowance
	P9031		Platelets, leukocytes reduced, each unit	8.00
	P9032		Platelets, irradiated, each unit	8.00
	P9033		Platelets, leukocytes reduced, irradiated, each unit	16.00
	P9034		Platelets, pheresis, each unit	25.00
	P9035		Platelets, pheresis, leukocytes reduced, each unit	16.00
	P9036		Platelets, pheresis, irradiated, each unit	8.00
	P9037		Platelets, pheresis, leukocytes reduced, irradiated, each unit	8.00
	P9038		Red blood cells, irradiated, each unit	8.00
	P9039		Red blood cells, deglycerolized, each unit	8.00
	P9040		Red blood cells, leukocytes reduced, irradiated, each unit	8.00
	P9041		Infusion, albumin (human), 5%, 50 ml	10.00
	P9043		Infusion plasma protein fraction (human), 5%, 50 ml	10.00
	P9044		Plasma, cryoprecipitate reduced, each unit	20.00
	P9046		Infusion, albumin (human), 25%, 20ml	10.00
	P9612		Catheterization for collection of specimen; single patient, all places of service	1.80
	Q0111		Wet mounts, including preparations of vaginal, cervical or skin specimens	2.40
	Q0111	FP	Wet mounts, including preparations of vaginal, cervical or skin specimens	2.40
	Q0112		All potassium hydroxide (KOH) preparations	2.40
	Q0113		Pinworm examination	5.10
	Q0114		Fern Test	9.60
	Q0115		Post-coital direct, qualitative examinations of vaginal or cervical mucous	12.23

Amended by R.2001 d.79, effective March 5, 2001.
 See: 32 N.J.R. 4167(a), 33 N.J.R. 781(c).
 Rewrote the section.
 Amended by R.2003 d.15, effective January 6, 2003.
 See: 34 N.J.R. 2676(a), 35 N.J.R. 230(c).
 Inserted HCPCS codes Q0111 WF and Q0116 WF.
 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.