

HUMAN SERVICES

DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES

Independent Clinical Laboratories

Proposed Readoption: N.J.A.C. 10:61

Authorized By: Jennifer Velez, Commissioner, Department of Human Services.

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

Calendar Reference: See Summary below for explanation of exception to rulemaking calendar requirements.

Agency Control Number: 13-P-05.

Proposal Number: PRN 2013-132.

Submit comments by November 15, 2013 to:

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The agency proposal follows:

Summary

Pursuant to N.J.S.A. 52:14B-5.1.c(2), N.J.A.C. 10:61, Independent Clinical Laboratories, will expire on December 4, 2013. The Department has reviewed these rules and finds that they are necessary, reasonable, adequate, efficient, understandable, and responsive to the purposes for which they were originally promulgated. The rules set forth requirements for the provision of independent clinical laboratory services to New Jersey Medicaid and NJ FamilyCare beneficiaries. The Department proposes to readopt N.J.A.C. 10:61.

Federal regulations at 42 CFR Part 493 require all independent clinical laboratories and other providers of laboratory services including, but not limited to, physicians, podiatrists, nurse midwives, dentists, independent clinics, hospitals, special hospitals, and nursing facilities, to meet Federal certification standards.

The chapter proposed for re-adoption contains three subchapters and an appendix, described as follows:

Subchapter 1 contains purpose and scope, definitions, scope of services, general requirements for provider participation, Medicare-Medicaid relationship, recordkeeping requirements, and basis of reimbursement.

Subchapter 2 contains Clinical Laboratory Improvement Amendments (CLIA) requirements, requirements for specific services, limitations on laboratory services, and laboratory rebates.

Subchapter 3 contains the purpose, scope, and general provisions for the reimbursement fees; Healthcare Common Procedure Coding System (HCPCS)

procedure codes and maximum fee allowance schedule for Level 1; HCPCS procedure codes, procedure description, and maximum fee allowance schedule for Level 2; HCPCS procedure codes, procedure description, and maximum fee allowance schedule for Level 3; and pathology and laboratory HCPCS codes qualifiers.

Appendix A contains information about the Fiscal Agent Billing Supplement.

The Department has determined that the comment period for this notice of proposal will be 60 days; therefore, pursuant to N.J.A.C. 1:30-3.3(a)5, this notice is excepted from the rulemaking calendar requirement.

Social Impact

In State Fiscal Year 2012, 121 independent laboratories provided services to approximately 76,000 Medicaid/NJ FamilyCare fee-for-service beneficiaries.

The rules proposed for readoption are expected to have a positive social impact on Medicaid/NJ FamilyCare fee-for-service beneficiaries, who will continue to receive needed services from independent laboratories. The rules proposed for readoption are expected to have a positive impact on Medicaid/NJ FamilyCare fee-for-service providers as the continuation of this chapter ensures that reimbursement is provided and that the providers are informed of requirements for the provision of independent laboratory clinic services as enrolled providers in the New Jersey Medicaid and NJ FamilyCare programs.

Economic Impact

During State Fiscal Year 2012, the Department spent approximately \$16 million (Federal and State share combined) to provide independent clinical laboratory services to approximately 76,000 Medicaid/NJ FamilyCare fee-for-service beneficiaries.

The rules proposed for re-adoption are not expected to have an economic impact on Department expenditures for the provision of services to eligible Medicaid/NJ FamilyCare fee-for-service beneficiaries because the reimbursement amounts are not being changed in this proposed re-adoption.

The rules proposed for re-adoption are expected to have a positive economic impact on providers because they will ensure that providers will continue to be reimbursed for the provision of independent clinical laboratory services.

There will be no economic impact on the beneficiaries because Medicaid/NJ FamilyCare beneficiaries are not required to pay for services, except as specified by NJ FamilyCare plans.

Federal Standards Statement

Section 1902(a)(9)(C) of the Social Security Act, 42 U.S.C. § 1396a(a)(9)(C), allows a State Medicaid program to cover and reimburse for independent clinical laboratory services. Federal regulations at 42 CFR 440.30 and 441.17 govern the provision of laboratory services to Medicaid/NJ FamilyCare beneficiaries.

Title XXI of the Social Security Act allows states the option of establishing a State Children's Health Insurance Program for targeted low-income children. New Jersey elected this option through implementation of the NJ FamilyCare program. Sections 2103(c)(1)(C) and 2110(a)(8) of the Social Security Act, 42 U.S.C. §§ 1397cc(c)(1)(C)

and 1397jj(a)(8), respectively, provide for laboratory services as part of a state Child Health Insurance Program.

Federal regulations at 42 CFR Part 493 require all independent clinical laboratories and other providers of laboratory services to meet Federal certification standards.

Section 1173(a) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires the use of a uniform reporting system for all health services facilities and organizations. See Federal regulations at 45 CFR 162.1002.

The Department has reviewed the Federal statutory and regulatory requirements and has determined that the rules proposed for readoption do not exceed Federal standards. Therefore, a Federal standards analysis is not required.

Jobs Impact

The Department does not anticipate that the rules proposed for readoption will result in the creation or loss of jobs in the State of New Jersey.

Agriculture Industry Impact

Since the rules proposed for readoption concern the provision of independent clinical laboratory services to Medicaid and NJ FamilyCare fee-for-service beneficiaries, the Department anticipates that the rules proposed for readoption will have no impact on the agriculture industry in the State of New Jersey.

Regulatory Flexibility Analysis

The rules proposed for readoption will affect only those providers of laboratory services who serve Medicaid and NJ FamilyCare beneficiaries. Most of these providers may be considered small businesses as the term is defined in the Regulatory Flexibility Act at N.J.S.A. 52:14B-17.

The rules proposed for readoption do not impose any additional reporting or recordkeeping requirements on providers because all laboratories are required to comply with existing Federal standards, including but not limited to, 42 CFR 493, which sets forth the conditions of the Clinical Laboratory Improvement Amendments of 1988, and the rules proposed for readoption do not add to this, beyond those procedural requirements needed for reimbursement for services rendered. There will be no need to hire additional professional staff because providers are already required to use the HCPCS codes to request reimbursement.

. These procedural requirements must be equally applicable to all providers, regardless of business size, because all providers must use appropriate procedures to receive reimbursement for services provided.

There should be no capital costs or annual compliance costs associated with the rules proposed for readoption.

Housing Affordability Impact Analysis

Since the rules proposed for readoption concern the provision of independent clinical laboratory services to Medicaid and NJ FamilyCare fee-for-service beneficiaries, the Department anticipates that the rules will have no impact on affordable housing nor will it have an impact on the average costs associated with housing.

Smart Growth Development Impact Analysis

Since the rules proposed for readoption concern the provision of independent clinical laboratory services to Medicaid and NJ FamilyCare fee-for-service beneficiaries, the rules will have no impact on housing production in Planning Areas 1 and 2, or within designated centers, under the State Development and Redevelopment Plan, and will have no impact on smart growth.

Full text of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 10:61.