N.J.A.C. 8:61

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CHAPTER 61. AIDS DRUG DISTRIBUTION PROGRAM; HIV COUNSELING AND HIV TESTING OF PREGNANT PERSONS; AND NEONATAL HIV TESTING

Title 8, Chapter 61 -- Chapter Notes

Statutory Authority

CHAPTER AUTHORITY:

N.J.S.A. 26:2-111.2; 26:4-129; 26:5C-1 et seq., particularly 26:5C-6, 8, and 20; and 30:4D-17.18a.

History

CHAPTER SOURCE AND EFFECTIVE DATE:

R.2025 d.008, effective December 11, 2024.

See: 56 N.J.R. 1654(a), 57 N.J.R. 29(a).

CHAPTER HISTORICAL NOTE:

Chapter 61, Acquired Immunodeficiency Syndrome, was adopted as R.1986 d.407, effective October 6, 1986. See: 18 N.J.R. 1512(a), 18 N.J.R. 2014(a).

Subchapter 2, Eligibility Criteria to Participate in the Retrovir Drug Program (now AIDS Drug Distribution Program), was adopted as emergency new rules by R.1987 d.437, effective October 7, 1987. See: 19 N.J.R. 2067(a). The provisions of R.1987 d.437 were readopted as R.1988 d.6, effective December 4, 1987. See: 19 N.J.R. 2067(a), 20 N.J.R. 89(b).

Pursuant to Executive Order No. 66(1978), Chapter 61 was readopted as R.1991 d.538, effective October 4, 1991. See: 23 N.J.R. 2245(b), 23 N.J.R. 3332(a).

Pursuant to Executive Order No. 66(1978), Chapter 61 was readopted as R.1996 d.509, effective October 4, 1996. As part of R.1996 d.509, Subchapter 3, HIV Counseling and Testing of Pregnant Women, and Subchapter 4, Disclosure of Information to Prospective Foster or Adoptive Parents by DYFS or Licensed Agency, were adopted as new rules, effective November 4, 1996. See: 28 N.J.R. 4019(a), 28 N.J.R. 4202(a), and 28 N.J.R. 4787(a). Chapter 61, Acquired Immunodeficiency Syndrome, expired on October 4, 2001.

Chapter 61, Attendance and Participation at School by Persons With HIV Infection; Aids Drug Distribution Program; HIV/AIDS Counseling and Testing of Pregnant Women for HIV; and Disclosure of Children's HIV/AIDS Status, was adopted as R.2005 d.3, effective January 3, 2005. See: 35 N.J.R. 5338(a), 37 N.J.R. 60(a).

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Subchapter 4, HIV Counseling and Testing of Pregnant Women, was repealed and Subchapter 4, Testing of Pregnant Woman and Newborns for HIV or Human Immunodeficiency Virus, was adopted as new rules by R.2010 d.139, effective July 6, 2010. See: 41 N.J.R. 3354(a), 42 N.J.R. 1375(a).

Pursuant to Executive Order No. 1(2010), the chapter expiration date was extended from January 3, 2010 until the completion of the review of administrative regulations and rules by the Red Tape Review Group, and until such time as the extended regulation or rule was readopted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. See: 42 N.J.R. 893(a).

Chapter 61, Attendance and Participation at School by Persons With HIV Infection; Aids Drug Distribution Program; HIV/AIDS Counseling and Testing of Pregnant Women for HIV; and Disclosure of Children's HIV/AIDS Status, was readopted as R.2010 d.196, effective August 18, 2010. See: 42 N.J.R. 893(a), 42 N.J.R. 2269(a).

In accordance with N.J.S.A. 52:14B-5.1b, Chapter 61, Attendance and Participation at School by Persons With HIV Infection; Aids Drug Distribution Program; HIV/AIDS Counseling and Testing of Pregnant Women for HIV; and Disclosure of Children's HIV/AIDS Status, was scheduled to expire on August 18, 2017. See: 43 N.J.R. 1203(a).

Chapter 61, Attendance and Participation at School by Persons With HIV Infection; Aids Drug Distribution Program; HIV/AIDS Counseling and Testing of Pregnant Women for HIV; and Disclosure of Children's HIV/AIDS Status, was readopted with technical changes, effective July 17, 2017. See: 49 N.J.R. 2796(a).

Chapter 61, Attendance and Participation at School by Persons With HIV Infection; Aids Drug Distribution Program; HIV/AIDS Counseling and Testing of Pregnant Women for HIV; and Disclosure of Children's HIV/AIDS Status, was readopted as R.2025 d.008, effective December 11, 2024. As a part of R.2025 d.008, Chapter 61 was renamed Aids Drug Distribution Program; HIV Counseling and HIV Testing of Pregnant Persons; and Neonatal HIV Testing; Subchapter 2, Participation and Attendance at School by Individuals with HIV Infection, and Subchapter 5, Disclosure of Information to Full-Time Caregivers, were repealed; Subchapter 1 was renamed General Provisions, Subchapter 3 was renamed Aids Drug Distribution Program and Health Insurance Premium Payment Program, Subchapter 4 was renamed Screening Pregnant Persons and Newborns for HIV Infection; Interventions to Reduce Perinatal HIV Transmission Rates; and Appendices A, B, and C were adopted as new rules effective January 6, 2025. See: Source and Effective Date. See, also, section annotations.

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SUBCHAPTER 1. GENERAL PROVISIONS

§ 8:61-1.1 Purpose and scope

- (a) The purpose of this chapter is to implement:
 - **1.** The State pharmaceutical benefits program, known as the AIDS Drug Distribution Program (ADDP), at N.J.S.A. 30:4D-17.16 through 17.18a, and the Health Insurance Premium Payment (HIPP) program;
 - 2. N.J.S.A. 26:5C-15 through 20; and
 - 3. N.J.S.A. 26:2-111.2.
- (b) This chapter applies to:
 - **1.** Applicants for participation, and persons seeking renewal of participation in the ADDP and the HIPP program;
 - 2. Health care providers who serve as primary caregivers;
 - **3.** Persons who have access to the HIV status of any person, including pregnant and/or recently postpartum persons, and/or their newborns; and
 - 4. Birthing facilities.
- **(b)** This subchapter is part of the State Sanitary Code and compliance is subject to N.J.S.A. 26:1A-10, 26:4-129, and 26:5C-14 and 18.

History

HISTORY:

New Rule by R.2025, d.008, effective January 6, 2025.

See: 56 N.J.R. 1654(a), 57 N.J.R. 29(a).

Former N.J.A.C. 8:61-1.1, "Definitions", recodified to N.J.A.C. 8:61-1.2.

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CHAPTER 61. AIDS DRUG DISTRIBUTION PROGRAM; HIV COUNSELING AND HIV TESTING OF PREGNANT PERSONS; AND NEONATAL HIV TESTING > SUBCHAPTER 1. GENERAL PROVISIONS

§ 8:61-1.2 Definitions

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

"AIDS" means "AIDS" as defined at N.J.S.A. 26:5C-1 et seq., especially at 5 and 15, as supplemented and modified by the HIV Case Definition.

"AIDS Drug Distribution Program" or "ADDP" means a program of the Department by which eligible individuals can receive prescription medications approved by the Federal Food and Drug Administration that prolong and/or enhance the lives of individuals with HIV infection from funds appropriated to the State from the Federal government.

"Birthing facility" means "birthing facility" as defined at N.J.S.A. 26:2-111.2.

"Centers for Disease Control and Prevention" or "CDC" means the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

"Commissioner" means the Commissioner of Health.

"Department" means the New Jersey Department of Health.

"Division" means the Division of HIV, STD, and TB Services within the Department, for which the contact information is Division of HIV, STD, and TB Services, New Jersey Department of Health, PO Box 363, Trenton, NJ 08625-0363, telephone (800) 624-2377 (this is a 24-hour toll-free telephone number), and telefacsimile (609) 984-6495.

"Drug Utilization Review Board" means the entity by that name established pursuant to N.J.S.A. 30:4D-17.16 through 17.18a, especially at 17.17a.

"Federal poverty guidelines" means:

- 1. The Annual Update of the HHS Poverty Guidelines, which are incorporated herein by reference, as amended and supplemented, that the Secretary of the United States Department of Health and Human Services annually issues and publishes in the Federal Register pursuant to 42 U.S.C. § 9902(2); and
- **2.** That are applicable and in effect as of the date an applicant applies for enrollment and/or the date an enrolled person applies for re-enrollment, in the ADDP or the HIPP program.

"Health care provider" means a person who holds a license pursuant to Title 45 of the Revised Statutes:

- 1. As a physician, an advanced practice nurse, a physician assistant, or a midwife; or
- 2. Whose licensed scope of practice includes the diagnosis and/or treatment of HIV.

"Health Insurance Premium Payment program" or "HIPP program" means a program by which the ADDP funds health insurance premium payments for persons living with HIV.

"HIV" means "HIV" as defined at N.J.S.A. 26:5C-1 et seq., especially at 26:5C-5, 15, and 21, as supplemented and modified by the HIV Case Definition.

"HIV Case Definition" means CDC, et al., Revised Surveillance Case Definition for HIV Infection--United States, 2014, MMWR, Vol. 63, No. RR-03 (April 11, 2014), available at https://www.cdc.gov/mmwr/indrr_2014.html, incorporated herein by reference, as amended and supplemented.

"HIV infection" means "HIV infection" as defined at N.J.S.A. 26:5C-1 et seq., especially at 26:5C-5, as supplemented and modified by the HIV Case Definition.

"HIV-related illness" means "HIV related illness" as defined at N.J.S.A. 26:5C-1 et seq., especially at 26:5C-5, as supplemented and modified by the HIV Case Definition.

"HIV-related test" means "HIV related test" as defined at N.J.S.A. 26:5C-1 et seq., especially at 26:5C-5, as supplemented and modified by the Testing Recommendations.

"HIV test" means "HIV test" as defined at N.J.S.A. 26:5C-1 et seq., especially at 26:5C-21, as supplemented and modified by the Testing Recommendations.

"Household" means "household" as defined at 42 CFR 435.603.

"Household income" means "household income" as defined at 42 CFR 435.603.

"Informed consent" means "informed consent" as defined at N.J.S.A. 26:5C-1 et seq., especially at 26:5C-5.

"MAGI-based income" means "MAGI-based income" as defined at 42 CFR 435.603.

"Parent" means:

- 1. A biological parent;
- 2. An adoptive parent;
- 3. A "resource family parent" as defined at N.J.S.A. 30:4C-26.4; and
- **4.** A person or an entity serving as guardian of the person of a minor or incapacitated person pursuant to an applicable statute, court rule, court order, or duly executed delegation of parental rights.

"Perinatal HIV Clinical Guidelines" means United States Department of Health and Human Services, Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission, et al., Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States, which is published in an electronic format that is updated regularly and frequently, as relevant changes in prevention and treatment recommendations occur (last updated January 31, 2024), available at https://clinicalinfo.hiv.gov/en/guidelines/perinatal, incorporated herein by reference, as amended and supplemented.

"Testing recommendations" means CDC, et al., Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings, MMWR, Vol. 55, No. RR-14 (September 22, 2006), available at https://www.cdc.gov/mmwr/indrr_2006.html, incorporated herein by reference, as amended and supplemented.

History

HISTORY:

Amended by R.2010 d.139, effective July 6, 2010.

See: 41 N.J.R. 3354(a), 42 N.J.R. 1375(a).

§ 8:61-1.2 Definitions

Rewrote definitions "AIDS" and "HIV"; and added definition "Clinical practitioner".

Notice of readoption with technical change, effective August 21, 2017.

See: 49 N.J.R. 2796(a).

Recodified from N.J.A.C. 8:61-1.1 by R.2025 d.008, effective January 6, 2025.

See: 56 N.J.R. 1654(a), 57 N.J.R. 29(a).

Rewrote the section.

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SUBCHAPTER 2. (RESERVED)

Title 8, Chapter 61, Subchapter 2. (RESERVED)

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PAYMENT PROGRAM

§ 8:61-3.1 Covered medications

Pursuant to N.J.S.A. 30:4D-17.17a, 17.18, and 17.18a, the Department of Human Services, in consultation with the AIDS/HIV Drug Utilization Review Committee of the Drug Utilization Review Board, and with the approval of the Commissioner of Health, shall determine the formulary of medications that the ADDP covers.

History

HISTORY:

Repeal and New Rule by R.2025 d.008, effective January 6, 2025.

See: 56 N.J.R. 1654(a), 57 N.J.R. 29(a).

Section was "Purpose; scope".

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§ 8:61-3.2 Clinical eligibility criteria

To be clinically eligible to participate in the ADDP, an applicant must meet the clinical criteria of the HIV Case Definition as determined by a health care provider.

History

HISTORY:

Recodified from N.J.A.C. 8:61-3.3 and amended by R.2025 d.008, effective January 6, 2025.

See: 56 N.J.R. 1654(a), 57 N.J.R. 29(a).

Former N.J.A.C. 8:61-3.2, "Coverage", repealed. Rewrote the section.

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§ 8:61-3.3 ADDP income and residency eligibility criteria

- (a) To be eligible to participate, or to renew one's participation, in the ADDP, an applicant shall be a permanent resident of New Jersey and have an annual household income that does not exceed 500 percent of the Federal poverty guidelines.
- **(b)** The Department will calculate an applicant's financial eligibility for participation in the ADDP based on the applicant's MAGI-based income.
- (c) ADDP eligibility is valid for 12 months from a participant's date of enrollment.
 - 1. The Division shall transmit written notice to participants annually that provides an application for renewal of enrollment and specifying the deadline and procedure for submission of renewal applications.
 - **2.** An applicant's case manager may assist participants in submission of renewal applications, as necessary.
- (d) Upon application for renewal of an applicant's enrollment in the ADDP, if the applicant's actual household income for the previous year exceeded 500 percent of the Federal poverty guidelines, but is not expected to exceed that amount in the upcoming year for which the applicant is seeking reenrollment, the Division will review on a case-by-case basis whether the applicant remains eligible for reenrollment in the ADDP, with the overriding consideration being the prevention of HIV transmission based on the likelihood that the applicant would continue to adhere to a medication regimen if not reenrolled, in view of the applicant's overall financial circumstances, and given the relative cost that the applicant would incur to obtain prescribed HIV medications if not reenrolled.
- **(e)** The ADDP program shall take necessary action to recover from a third party, the full amount of payments it may have made to the third party, on behalf of a participant, during a period of the participant's ineligibility, when appropriate.
- **(f)** Upon request of an applicant, the Division will assist an applicant to enroll in Medicare Part D Low Income Subsidy (LIS), pursuant to 20 CFR Part 418, Subpart D, and 42 CFR Part 423, upon the applicant's submission of all income and asset information that is necessary to apply.
 - **1.** The Division may provide payments from ADDP funds for LIS premiums and medication copayments for enrolled participants, subject to the availability of funding.
- **(g)** The Division shall determine an applicant's New Jersey residency in accordance with the residency standards established for the PAAD program at N.J.A.C. 10:167-6.4.

History

HISTORY:

Recodified from N.J.A.C. 8:61-3.4 and amended by R.2025 d.008, effective January 6, 2025.

See: 56 N.J.R. 1654(a), 57 N.J.R. 29(a).

Former N.J.A.C. 8:61-3.3, "Clinical eligibility", recodified to N.J.A.C. 8:61-3.2. Rewrote the section.

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§ 8:61-3.4 Third-party coverage

Individuals who are eligible to receive covered medications from entitlement programs or third-party payers are not eligible to receive benefits pursuant to the ADDP.

History

HISTORY:

Recodified from N.J.A.C. 8:61-3.6 and amended by R.2025 d.008, effective January 6, 2025.

See: 56 N.J.R. 1654(a), 57 N.J.R. 29(a).

Former N.J.A.C. 8:61-3.4, "Income eligibility", recodified to N.J.A.C. 8:61-3.3. Rewrote the section.

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§ 8:61-3.5 ADDP application process

- (a) An applicant for enrollment in the ADDP shall submit to the Division, a completed application and supporting documentation in the forms at chapter Appendices A, B, and C, "Application for Participation in the AIDS Drug Distribution Program" (DHSTS-27), "Certification of Licensed Health Care Provider" (DHSTS-37); and "Application for Participation in the Health Premium Payment Program" (DHSTS-47).
 - **1.** ADDP application and certification forms can be obtained by calling the Division, toll-free, at 1-877-613-4533, or from the Department's forms page at www.nj.gov/health/forms.
- **(b)** The Division will notify an applicant, in writing, upon determining the applicant's eligibility, and, if an applicant is eligible, the Division will notify the applicant's health care provider of the applicant's enrollment in the ADDP.

History

HISTORY:

Recodified from N.J.A.C. 8:61-3.7 by R.2025 d.008, effective January 6, 2025.

See: 56 N.J.R. 1654(a), 57 N.J.R. 29(a).

Former N.J.A.C. 8:61-3.5, "Residence", repealed. Rewrote the section.

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§ 8:61-3.6 Health Insurance Premium Payment program (HIPP program) eligibility and application process

- (a) Eligibility for the HIPP program is contingent upon an applicant's active enrollment in the ADDP.
- (b) An applicant for participation in the HIPP shall:
 - **1.** Apply through a Ryan White medical case manager in the practice of the applicant's health care provider; or
 - **2.** Telephone the Division at (800) 353-3232, and the Division will assign a regional Ryan White medical case manager to organize submission of an enrollment application on behalf of the applicant.
- **(c)** The applicant's case manager will complete a HIPP Program Application Form in the form at chapter Appendix C, incorporated herein by reference, using information that the applicant supplies, and submit the application to the Division.
 - **1.** An HIPP program application form can be obtained from HIV treatment sites or by calling the Division, toll free, at (800) 353-3232.

History

HISTORY:

New Rule by R.2025 d.008, effective January 6, 2025.

See: 56 N.J.R. 1654(a), 57 N.J.R. 29(a).

Former N.J.A.C. 8:61-3.6, "Third party coverage", recodified to N.J.A.C. 8:61-3.4.

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