

Pursuant to the authority vested in the Commissioner of Health by sections 201(1)(o), 201(1)(p) and 2776(1)(e) of the Public Health Law, the titles of part 43 and subpart 43-2 and sections 43-2.1, 43-2.2, 43-2.3, 43-2.4, and 43-2.5 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

The title of part 43 is amended to read as follows: State Aid for Tuberculosis and [the AIDS Drug Assistance Program] Uninsured Care Programs

The title of subpart 43-2 is amended to read as follows: [HIV] Uninsured Care Programs

Section 43-2.1 is amended to read as follows:

Section 43-2.1 Scope. These regulations govern the application and eligibility determination process for the [HIV] Uninsured Care Programs and establish the rights and responsibilities of applicants, participants, providers, and contractors in that process.

Subdivisions (e) and (f) of section 43-2.2 are amended to read as follows:

(e) Period of coverage. Coverage for assistance for each individual program component is effective as specified in the individual's notification of eligibility. Coverage will terminate under the following circumstances:

(1) the applicant indicates in writing that [he/she] they no longer need[s] or desire[s] assistance;

- (2) the department determines that a change in the participant's circumstances or residence has affected [his/her] their eligibility;
 - (3) the participant has died or cannot be located; and
 - (4) funding for the [HIV] Uninsured Care Programs is exhausted.
- (f) Program means the [HIV] Uninsured Care Programs, as defined by the AIDS Institute, including the following service components:
- (1) AIDS Drug Assistance Program, which provides coverage of medications;
 - (2) ADAP Plus, which provides coverage for ambulatory care services;
 - (3) ADAP Plus Insurance Continuation, which pays for insurance premiums for eligible individuals who have cost effective insurance policies; and
 - (4) the HIV Home Care Program, which provides coverage for home care services.

Subdivision (j) of section 43-2.2 is amended to read as follows:

(j) Provider means a medical provider, including a pharmacy, hospital, clinic, [physician] clinical practitioner, laboratory or home health care agency.

Section 43-2.3 is amended to read as follows:

Section 43-2.3 Confidentiality. All information which may identify an applicant which is received by the program will be confidential and can only be used when necessary for supervision, monitoring or administration of the program. Information received by any contractor, his agents, employees, or by any other person or agency concerning applicants or participants in the program is confidential and may not be disclosed without the written approval of the [HIV] Uninsured Care Program [Director] director, who shall

approve disclosure only in conformance with Article 27-F of the Public Health Law and the federal standards with respect to the privacy and security of individually identifiable health information contained in Part 164 of Title 45 of the Code of Federal Regulations.

Paragraph (1) of subdivision (c) of section 43-2.4 is amended to read as follows:

(1) name, [sex] gender, date of birth, social security number, marital status, address and telephone number of the applicant;

Section 43-2.5 is amended to read as follows:

Section 43-2.5 Eligibility for coverage.

(a) An applicant must be confirmed as medically eligible to participate in the program.

The Department of Health will confirm medical eligibility based upon information received from the applicant [or] and the applicant's [physician] clinical practitioner or [the physician's] their designee. The applicant's [physician] clinical practitioner or [the physician's] their designee will be required to submit information regarding an applicant's medical condition on a State-approved form consistent with their scope of practice.

(b) Financial eligibility will be based upon the available household income.

(1) In order to be eligible, an applicant's available household income must be equal to or less than [435%] 500% of the amount under the annual United States Department of Health and Human Services poverty guidelines for the applicant's family size. Federal poverty guidelines are published annually by the Department of Health and Human Services in the Federal Register.

(2) Applicants must provide income information for a reasonable period prior to application. Applicants who are self-employed must provide business records for the three months prior to application indicating type of business, gross income and net income.

[(c) Liquid resources shall be reviewed to determine their availability in determining eligibility for the program. In order to be eligible, an applicant's liquid resources must be less than \$25,000. Liquid resources are cash or those assets which can be readily converted to cash such as bank accounts, lump sum payments, i.e., stocks, bonds and mutual fund shares.]

[(d)] (c) Full and proper use shall be made of existing public and private medical and health services and facilities for obtaining therapeutic drugs, medical services, and related supplies and equipment for the treatment or prevention of HIV or AIDS.

[(e)] (d) An applicant or recipient of assistance may be required as a condition of eligibility or continued eligibility to assign any rights [he/she] they may have for coverage benefits under any health insurance policy or group health plan to the department.

[(f)] (e) In order to be eligible for ADAP Plus Insurance Continuation, an applicant must have:

(1) a health insurance policy that is determined to be cost effective by the department, based on the cost of premiums, limitations of coverage (i.e., deductible, caps, co-payments) and estimates of the monetary value of projected utilization and reimbursement under the insurance policy; and

(2) a premium cost that is more than 4% of the [applicants] applicant's available household income, if the [applicants] applicant's available household income is greater than 200% of the amount under the annual United States Department of Health and Human Services poverty guidelines for the applicant's family size.]; and

(3) an employer contribution of 50% or more of the total cost of the health insurance premium, if the applicant is employed full-time and eligible for employer sponsored health insurance.]

REGULATORY IMPACT STATEMENT

Statutory Authority:

Statutory authority for the Uninsured Care Programs exists under Public Health Law (PHL) Section 2776(1)(e) which authorizes the AIDS Institute to promote the availability of supportive services for affected persons. PHL Sections 201(1)(o) and 201(1)(p) permit the Department to receive and expend funds available for public health. The Department promotes therapeutic services related to communicable diseases affecting public health under the authority of PHL Section 201(1)(h). PHL Section 206(3) permits the Commissioner to enter into contracts to carry out the general intent and purposes of the Public Health Law.

Legislative Objective:

The statutes enable the Commissioner to receive and expend funds for the public health, including funds necessary to provide medications, medical treatment and other supportive services to persons with or at risk of acquiring HIV.

Needs and Benefits:

The Uninsured Care Programs are funded by federal and state appropriations administered by the New York State Department of Health (NYSDOH). Through the Uninsured Care Programs, the NYSDOH offers selected drugs, ambulatory care, home care services and insurance continuation payments at no charge to medically and financially eligible individuals who are residents of New York State. The NYSDOH determines eligibility for the Uninsured Care Programs and issues identification cards to authorized program participants, thereby enabling pharmacies and health care providers

to dispense drugs and provide services at established rates to authorized program participants.

The proposed regulatory action will remove barriers to care and update the name and definition of the programs. Specifically, the proposed regulatory action will:

1. Update the income criteria by establishing eligibility at 500 percent of the Federal Poverty Level (FPL). The income criteria has not been updated since 2010. The current income criteria is lower than other high-incidence states and lower than all surrounding states.
2. Eliminate the inclusion of liquid assets as a resource that must be reviewed when determining eligibility. New York State is one of only three states or territories to impose an asset test on applicants.
3. Eliminate the 50% employer share of cost requirement for premium payment assistance. New York State is the only state to require employers to contribute 50% to the cost of health care coverage premiums.
4. Change the name of the program from “HIV Uninsured Care Programs” to “Uninsured Care Programs,” and change the definition of “Program” to read “Program means the Uninsured Care Programs as defined by the AIDS Institute.” Since the regulations were last modified, the system of services for uninsured and underinsured persons has expanded to include the Pre-Exposure Prophylaxis Assistance Program (PrEP-AP), which serves persons at high risk of acquiring HIV; the Hepatitis C Assistance Program (HepCAP), which serves persons with hepatitis C receiving services through funded programs; the Naloxone Co-Payment Assistance Program, which covers prescription co-payments for persons

obtaining naloxone at pharmacies; and the Rapid Treatment Program (RapidTx), which provides immediate access to anti-retroviral treatment for persons newly diagnosed with HIV or returning to care. The name “Uninsured Care Programs” is more appropriate since the programs now include initiatives serving HIV-negative persons. Adding “as defined by the AIDS Institute” to the program definition is appropriate because the system of services for uninsured and underinsured persons has expanded and may continue to expand. Coverage of services is revised based on available funding, allowability under federal and state funding sources, and the changing profiles of the epidemics managed by the AIDS Institute.

5. In the definition of “provider,” change the word “physician” to “clinical practitioner” to allow participation in the program by hospitals, clinics, practitioners, laboratories, and home health care agencies.

Costs:

The proposed amendments will have no impact on the costs of the program to the State. Any additional costs associated with the broader scope of the program are funded through federal grants.

Costs to Local Governments:

There is no cost to local governments associated with this proposed rule change. . The additional cost of providing medical benefits to individuals who are eligible for the programs due to annual cost of living increments in Federal Poverty Level (FPL) will be paid for using federal funds allocated through the Ryan White Treatment Extension Act of 2009. For individuals who are underinsured, the Programs will mitigate increases in

costs to the programs by coordinating medical benefit coverage with other health care coverage.

Costs to Private Regulated Parties:

No additional costs will be incurred by Private Regulated Parties enrolled in the program. A single application may be utilized for all components of the programs. The application includes the same data elements previously required for the HIV Uninsured Care Programs. Practitioners have been and will continue to be required to submit information to verify patients' medical eligibility. Enrolled providers must submit claim forms that include data elements from the standard Medicaid claim format.

The cost to a newly enrolled health care provider to submit the information requested on the claim form is dependent on the number of program participants being served and the frequency of services. We estimate that costs to providers to submit claims to the program will entail an average of approximately 15 minutes per month for each consequently reimbursed participant served during the month.

Costs to the Department of Health:

No new costs will be incurred by the NYSDOH by these proposed regulatory revisions. The additional cost of providing medical benefits to individuals who are eligible for the programs due to annual cost of living increments in Federal Poverty Level (FPL) will be paid for using federal funds allocated through the Ryan White Treatment Extension Act of 2009. For individuals who are underinsured, the Programs will mitigate increases in costs to the programs by coordinating medical benefit coverage with other health care coverage.

Local Government Mandates:

The proposed regulation relates to an optional program for pharmacies, Article 28 facilities, practitioners, home care agencies and laboratories. There are no local government mandates associated with this proposed rule change.

Paperwork:

No new paperwork for referring clinicians or pharmacies is necessitated by these changes. Clinicians continue to provide information to the NYSDOH to assess the medical eligibility of the applicant, and pharmacies must continue to submit claims in the manner specified by the NYSDOH.

Health care providers must submit claim forms in the manner specified by the NYSDOH. The claim forms include data elements consistent with those maintained by the providers for claiming Medicaid reimbursement. Home care providers must also submit care plans for pre-approval of services for individuals in a format analogous to that used by the Medicaid program.

Duplications:

These regulations do not duplicate any existing State or federal requirements.

Alternatives:

There are no reasonable alternatives to enacting these regulation changes to eligibility and reimbursement procedures.

Federal Standards:

These regulations do not exceed any minimum standard of the federal government.

Compliance Schedule:

These regulations will be effective upon publication of a Notice of Adoption in the New York State Register.

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

**STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS**

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

**STATEMENT IN LIEU OF
JOB IMPACT STATEMENT**

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (Department) received one comment during the public comment period from the New York City Department of Health and Mental Hygiene (“NYCDOHMH”).

Comment:

The comment expressed support for the proposed amendments to Subpart 43-2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York. Specifically, NYCDOHMH supported: changing the program name to “Uninsured Care Programs” (UCP) to reflect the scope of the programs; expanding the UCP financial eligibility from 435 percent of the Federal Poverty Level (FPL) to up to 500 percent FPL; eliminating the required employer contribution of 50 percent or more of the total cost of the health insurance premium for the employee to be eligible for premium payment assistance; and the amendments reflecting gender neutrality, replacing binary language, and replacing “physician” with “clinical practitioner” to describe authorized providers.

Response:

These comments in support are noted by the Department. No changes have been made to the regulations in response to these comments.