

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 1) Heading of the Part: AIDS Drug Assistance Program
- 2) Code Citation: 77 Ill. Adm. Code 692
- 3)

<u>Section Numbers:</u>	<u>Proposed Action:</u>
692.5	Amend
692.6	Amend
692.10	Amend
- 4) Statutory Authority: Ryan White HIV/AIDS Treatment Extension Act of 2009 [Public Law 111-87]; Section 315 of the Civil Administrative Code of Illinois [20 ILCS 2310/315]
- 5) A Complete Description of the Subjects and Issues Involved:

These amendments result from the recent decision of the U.S. Department of Health and Human Services (DHHS) to suspend enrollment into pre-existing condition insurance plans (PCIP), which functioned as a bridge for those uninsured Illinoisans to obtain creditable health insurance coverage for the care of their health conditions. The AIDS Drug Assistance Program (ADAP) used the Illinois PCIP to assist those who were outside the 300% federal poverty level (FPL) threshold, not to exceed 500% (FPL), to ensure that this population had access to life sustaining medications for the treatment of HIV and AIDS. With the suspension of the Illinois-operated PCIP a unique cohort of at-risk Illinoisans will go without regular HIV pharmaceutical therapies that will sustain quality of life and in some case enhance potential life mortality.

This rule will secure the bridge to the population of Illinois citizens who now have no affordable access to drug coverage with the suspension of Illinois PCIP. These rules will function as a bridge to the Affordable Care Act's full implementation on January 1, 2014, when all Illinoisans will either migrate to expanded Medicaid (if legislatively approved by the assembly) or the health insurance market place. Until January 1, 2014, it is critical that the AIDS Drug Assistance Program continues to function as a safety net for a population of uninsured clients that would have had access to insurance through the Illinois PCIP until DHHS suspended this program starting March 2, 2013.

This proposed rulemaking also "grandfathers in" applicants who were enrolled in ADAP on July 1, 2011, in the 301-500% FPL income bracket into ADAP on a go-forward basis, as long as the applicant's re-certifications are complete and submitted on time and do not exceed 500% FPL. If an applicant within this cohort is closed from the program due to

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

failure to reapply on time, then the applicant will be assessed using the 300% FPL eligibility limit. A definition for the ADAP program is also being added.

The rulemaking removes all language associated with Illinois Cares Rx (ICRx), which was eliminated by the State on July 1, 2012. ICRx was a state-operated pharmaceutical assistance program that ADAP coordinated to ensure that ADAP was “payer of last resort.”

The economic effect on this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

- 6) Published studies or reports, and sources of underlying data used to compose this rulemaking:
- 7) Will this rulemaking replace any emergency rulemaking currently in effect? Yes
- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this rulemaking contain incorporations by reference? Yes
- 10) Are there any other proposed rulemakings pending on this Part? No
- 11) Statement of Statewide Policy Objectives: This rulemaking does not create or expand a State Mandate.
- 12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking:

Interested persons may present their comments concerning this rulemaking within 45 days after the publication of this issue of the *Illinois Register* to:

Susan Meister
Division of Legal Services
Illinois Department of Public Health
535 W. Jefferson St., 5th floor

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH
NOTICE OF PROPOSED AMENDMENTS

Springfield, Illinois 62761

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- 13) Initial Regulatory Flexibility Analysis:
- A) Types of small businesses, small municipalities and not for profit corporations affected: None
 - B) Reporting, bookkeeping or other procedures required for compliance: None
 - C) Types of professional skills necessary for compliance: None

- 14) Regulatory Agenda on which this rulemaking was summarized:

This rule was not included on either of the two most recent Regulatory Agendas because the need for the rulemaking was not apparent when the Regulatory Agendas were prepared.

The text of the Proposed Amendments begins on the next page.

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER k: COMMUNICABLE DISEASE CONTROL AND IMMUNIZATIONS

PART 692
AIDS DRUG ASSISTANCE PROGRAM

Section

692.5	Definitions
692.6	<u>Incorporated and Referenced Materials</u>
692.10	Drugs to Prolong the Lives of Non-Medicaid Persons with Acquired Immunodeficiency Syndrome (AIDS) or Human Immunodeficiency Virus (HIV) Infection
692.15	Application Requirements
692.16	Non-Discrimination
692.APPENDIX A	2013 Poverty Income Guidelines
692.APPENDIX B	Ryan White HIV/AIDS Treatment Extension Act of 2009 Sliding Fee Scale

AUTHORITY: Implementing the Ryan White HIV/AIDS Treatment Extension Act of 2009 [Public Law 111-87], and authorized by Section 315 of the Civil Administrative Code of Illinois [20 ILCS 2310/315].

SOURCE: Emergency rule adopted at 15 Ill. Reg. 14699, effective September 30, 1991, for a maximum of 150 days; adopted at 16 Ill. Reg. 4052, effective February 27, 1992; emergency amendment at 17 Ill. Reg. 12913, effective July 23, 1993, for a maximum of 150 days; emergency expired December 20, 1993; amended at 18 Ill. Reg. 1427, effective January 20, 1994; amended at 18 Ill. Reg. 17678, effective November 30, 1994; amended at 20 Ill. Reg. 7531, effective May 15, 1996; emergency amendment at 20 Ill. Reg. 8353, effective June 4, 1996, for a maximum of 150 days; emergency expired November 1, 1996; amended at 21 Ill. Reg. 1203, effective January 10, 1997; amended at 22 Ill. Reg. 14468, effective July 24, 1998; amended at 24 Ill. Reg. 11876, effective August 1, 2000; emergency amendment at 35 Ill. Reg. 16105, effective September 26, 2011, for a maximum of 150 days; amended at 36 Ill. Reg. 3909, effective February 22, 2012; preemptory amendment at 37 Ill. Reg. 2563, effective February 15, 2013; emergency amendment at 37 Ill. Reg. _____, effective _____ for a maximum of 150 days; amended at 37 Ill. Reg. _____, effective _____.

Section 692.5 Definitions

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

AIDS Drug Assistance Program” or “ADAP” means a program that provides drugs to prolong the lives of low income persons with Acquired Immunodeficiency Syndrome (AIDS) or Human Immunodeficiency Virus (HIV) infection who are not eligible under Article V of the Illinois Public Aid Code for Medical Assistance. (Section 2310-315(13) of the Civil Administrative Code of Illinois)

“CD4 count” means the measurement of the number of CD4 cells in a sample of blood, which tells how strong the immune system is and indicates the stage of HIV disease.

"Department" means the Illinois Department of Public Health.

“Creditable coverage” means coverage of an individual as defined in 45 CFR 146.113(a)(1) (Public Welfare: Rules relating to creditable coverage).

“Extra Help Program” means a federal program that assists very low income (less than \$1,000/month) Medicare Part D eligible individuals with their prescription drug coverage. The program pays Medicare Part D premiums and all copayments except \$2 and \$3 on generic and brand, respectively. The program was established by the Patient Protection and Affordable Care Act (P.L. 111-148).

~~“Illinois Cares Rx” means a State program that provides prescription drug assistance to low income senior citizens and disabled persons, obtainable through the Department of Healthcare and Family Services (HFS).~~

“Medicaid” means the State-managed program under the federal Social Security Act [42 USC 1396] that pays medical care expenses for low-income individuals, including those with HIV/AIDS.

“Medicare” means the federal program under the Social Security Act [42 USC 1395] that pays for certain health care expenses for people aged 65 or older. Enrolled individuals must pay deductibles and co-payments.

“Viral Load” means a measurement of human immunodeficiency virus (HIV) in a sample of blood or other body fluids.

(Source: Amended at 37 Ill. Reg. _____, effective _____)

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

Section 692.6 Incorporated and Referenced Materials

The following materials are incorporated or referenced in this Part:

- a) Illinois Statutes
 - 1) Civil Administrative Code of Illinois [20 ILCS 2310]
 - 2) Illinois Public Aid Code [305 ILCS 5]
- b) Federal Statutes
 - 1) Ryan White HIV/AIDS Treatment Extension Act of 2009 (P.L. 111-87)
 - 2) Patient Protection and Affordable Care Act (P.L. 111-148)
 - 3) Social Security Act (42 USC 1395 and 1396)
- c) Illinois Administrative Rules
 - Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100)
- d) Federal Regulations
 - 45 CFR 146.113(a)(1) (2012)(Public Welfare: Rules relating to creditable coverage)

(Source: Amended at 37 Ill. Reg. _____, effective _____)

Section 692.10 Drugs to Prolong the Lives of Non-Medicaid Persons with Acquired Immunodeficiency Syndrome (AIDS) or Human Immunodeficiency Virus (HIV) Infection

Drugs provided under this Part are paid for on behalf of low-income individuals with acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV).

- a) Medical requirements. To qualify for services under this Part, a person shall have been enrolled in the AIDS Drug Assistance Program (ADAP) as of June 4, 1996, or:

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

- 1) Apply to the Department for acceptance for ADAP and comply with all recertification requirements, which occur every six months from the point of enrollment; and
 - 2) Be diagnosed as having AIDS or HIV through submission of a CD4 and viral load laboratory result that was obtained within six months prior to the date of application. For recertification, the applicant shall provide the most recent CD4 and viral load test results, which must be obtained within six months prior to any recertification date.
- b) Financial and insurance requirements
- 1) Applicants with no active prescription insurance coverage at the time of enrollment shall qualify financially with anticipated gross monthly income, as determined by the Department, at or below 300% of the most recent Federal Poverty Level (FPL) Guidelines published annually by the U.S. Department of Health and Human Services for the size of the household (see Appendix A);
 - 2) Applicants with active prescription coverage at the time of enrollment shall qualify financially with anticipated gross monthly income, as determined by the Department, at or below 500% of the most recent Federal Poverty Level Guidelines for the size of the household.
 - A) The applicant's health insurance provider must be willing to participate with the Department's contracted dispensing pharmacy for dispensing and billing purposes and only for drugs on the current ADAP formulary.
 - B) Only 30-day prescription fills will be accepted. If an applicant is planning to travel outside of Illinois for two to three months and needs a longer prescription fill, the applicant shall obtain prior approval from the ADAP for a medication exception. The applicant shall provide a clear copy of the front and back of all prescription insurance cards.
 - C) Applicants who were enrolled in ADAP on July 1, 2011, in the 301-500% FPL income bracket shall be grandfathered into ADAP

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

on a go-forward basis, as long as the applicant's re-certifications are complete and submitted on time and do not exceed 500% FPL. If an applicant within this cohort is closed from the program due to failure to reapply on time, then the applicant will be assessed using the 300% FPL eligibility limit.

- D) Applicants in the 301-500% FPL income bracket who have not been covered under creditable coverage for a continuous six month period prior to the date of application, but would have been eligible for a creditable coverage program recently offered under a State or federal government entity will be assessed on the same standard as those with active prescription coverage.
- 3) Applicants shall not be eligible for the Medical Assistance Program (Medicaid) on the date that drugs are obtained (individuals with financial/medical assistance applications pending or individuals in spend down unmet status may participate).
- 4) Applicants shall not be eligible for payment for prescription drugs from any other governmental entity.
- 5) If eligible for Medicare Part D, the applicant shall provide a clear copy of both the front and back of the Medicare Part D insurance card.
- 6) If enrolled in a Medicare Supplement plan (Medigap), the applicant shall provide a clear copy of both the front and back of the Medicare Supplement insurance card.
- 7) If eligible for federal Extra Help ~~or Illinois Cares Rx Plan (ICRx)~~, the applicant shall apply to that program ~~both programs~~. Approval or denial documentation shall be provided to the ADAP ~~as well as a clear copy of both the front and back of the ICRx card;~~
- c) Residency requirement. The applicant shall be a legal resident of Illinois as defined by Section 2-10 of the Illinois Public Aid Code [305 ILCS 5/2-10], except that:
- 1) The provision of Section 2-10 of the Illinois Public Aid Code stating that

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

applicants for or recipients of public aid must meet the requirements for duration of residence contained in applicable Sections of the Public Aid Code shall not apply to this Part; and

- 2 The provision of Section 2-10 of the Illinois Public Aid Code regarding recipients of aid under Article III, IV, or VI [305 ILCS 5/Art. III, IV or VI] shall apply to any recipient of services under the ADAP.
- d) Persons enrolled in the ADAP shall reapply every six months to continue receiving drugs through the ADAP.
 - 1) Renewal applications shall be complete, with all fields on the application filled out, shall include all required support documentation and shall be received by the Department at least three business days prior to the expiration date of the client's current enrollment.
 - 2) If the Department does not receive a renewal application at least three business days prior to the expiration date of the client's current enrollment, the client will be removed from the ADAP and will be required to meet the eligibility requirements of subsections (a) through (c) of this Section to continue receiving drugs through the ADAP.
 - e) The Department shall suspend a client's enrollment in the ADAP under the following circumstances:
 - 1) Submittal of fraudulent application information by an applicant or client;
 - 2) Failure to submit a completed application at least three business days prior to the expiration date of the client's current enrollment; or
 - 3) Failure to use a minimum of one drug from any category of the ADAP formulary within 90 days after enrollment to the ADAP.
 - f) Subject to the availability of funds, the Department may implement cost control measures at any time to ensure the long-term sustainability of the program.
 - g) All drugs provided under the ADAP have been approved by the federal Food and Drug Administration. The Department will request the advice of the medical

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

issues subcommittee of the Ryan White ADAP Medical Issues Advisory Board when necessary to assist with determining which drugs will be covered, based on criteria that include the medical appropriateness of the drug for treatment of HIV/AIDS and associated complications. The following categories of drugs may be covered under the ADAP.

- 1) Category I - Drugs for Anti-Retroviral Therapy;
 - 2) Category II - Drugs for Pneumocystis jiroveci (carinii) pneumonia (PCP) Prophylaxis and Treatment;
 - 3) Category III - Drugs for Prophylaxis and Treatment of Opportunistic Infections and Anti-Microbials;
 - 4) Category IV - Drugs for Treatment of Neoplasms; and
 - 5) Category V - Other Drugs Requiring Prior Approval.
- h) All prescriptions shall be filled by the Department's pharmacy contractors.
- i) The Department may require participants to pay a copayment for prescriptions received. If a copayment is charged, it shall not exceed the sliding fee structure specified in Part B of the Ryan White HIV/AIDS Treatment Extension Act of 2009 (see Appendix B).
- j) The Department will make a disposition and issue a written decision on an application filed pursuant to this Section within 30 business days after the date the Department receives the application. The Department will make a disposition and issue a written decision on a renewal application filed pursuant to this Section within 30 business days after the date the Department receives the completed application. An individual may appeal the Department's denial of his/her application in accordance with Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100).

(Source: Amended at 37 Ill. Reg. _____, effective _____)