

ILLINOIS REGISTER

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF EMERGENCY AMENDMENTS

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

<u>Section Numbers:</u>	<u>Emergency 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) Effective Date of Amendment:
- 6) If this emergency rulemaking is to expire before the end of the 150-day period, please specify the date on which it is to expire:
- 7) Date filed with the Index Department:
- 8) A copy of the adopted amendment, including any material incorporated by reference, is on file in the agency's principal office and is available for public inspection.
- 9) Reason for Emergency: The emergency nature of these amendments results 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 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 cases enhance potential life mortality. This emergency 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 General Assembly) or the health insurance market place. These emergency rules are critical to bridging a group of underserved and disenfranchised population to the full implementation of the Affordable Care Act on January 1, 2014. Until January 1, 2014, it is critical that AIDS Drug Assistance Program continues to function as a safety net for a population of uninsured clients that would have

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had access to insurance through the Illinois PCIP until DHHS suspended this program starting March 2, 2013. The short notice from DHHS (February 21, 2013) prevented the Illinois Department of Public Health from moving efficiently moving through the regular rulemaking process.

- 10) A Complete Description of the Subjects and Issues Involved: The Illinois Department of Public Health is adding a definition of what is considered “creditable coverage”; those applicants 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 the State or federal government entity, will be assessed on the same standard as those with active prescription coverage, which is 500% of the federal poverty level. This language ensures that those at the lowest end of economic brackets in the State, who are uninsured and suffering with a chronic/life threatening health condition (HIV), are provided a safety net for the pharmaceutical therapy coverage through the AIDS Drug Assistance Program.
- 11) Are there any proposed amendments to this Part pending? Yes

<u>Section Numbers</u>	<u>Proposed Action</u>	<u>Illinois Register Citation</u>
692.5	Amend	
692.6	Amend	
692.10	Amend	

- 12) Statement of Statewide Policy Objectives: This rulemaking will not create or expand a State Mandate.
- 13) Information and questions regarding these amendments shall be directed to:

Susan Meister
Administrative Rules Coordinator
Department of Public Health
535 W. Jefferson St., 5th Floor

(217)782-2043

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The full text of the emergency amendments begins on the next page:

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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

EMERGENCY

692.6 [Incorporated and](#) Referenced Materials

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

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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 (P.L. 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; peremptory amendment at 37 Ill. Reg. 2563, effective February 15, 2013; emergency amendment at 37 Ill. Reg. _____, effective March 18, 2013, for a maximum of 150 days.

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Section 692.5 Definitions

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"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.

["Creditable coverage" means coverage of an individual as defined in 45 CFR 146.113\(a\)\(1\) \(Public Welfare: Rules relating to creditable coverage\).](#)

"Department" means the Illinois Department of Public Health.

"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](#) age 65 or older. Enrolled [individuals](#) must [pay deductibles](#) and co-payments.

"Prescription insurance" means insurance paid for or provided by an employer, family member or the applicant that covers prescription medications.

"Viral load" means a measurement of human immunodeficiency virus (HIV) in a sample of blood or other body fluids.

(Source: Amended by emergency rulemaking at 37 Ill. Reg. _____, effective March 18, 2013, for a maximum of 150 days)

Section 692.6 Incorporated and Referenced Materials

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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 by emergency rulemaking at 37 Ill. Reg. _____, effective March 18, 2013, for a maximum of 150 days)

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

EMERGENCY

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) Eligibility 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:

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- 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 and be currently receiving HIV care, including having received a viral load test result and CD4 count within the six months prior to the date of the application or recertification.
- 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% FPL of the most recent Federal Poverty 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% FPL 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 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 on a go-forward basis, as long as the applicant's recertifications 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

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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 spenddown unmet status may participate).
 - 4) If eligible for Medicare Part D, the applicant shall enroll in Medicare Part D and provide information on the Part D coverage plan.
 - 5) If enrolled in a Medicare Supplement plan (Medigap), the applicant shall provide information on Medigap plan and coverage.
 - 6) If eligible for federal Extra Help or Illinois Cares Rx Plan (ICRx), the applicant must enroll and provide information on coverage.
- c) Residency requirement. The applicant shall be a legal resident of Illinois, as defined by Section 2-10 of the Illinois Public Aid Code, except that:
- 1) The provision of Section 2-10 of the Illinois Public Aid Code stating that 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 shall apply to any recipient of services under ADAP.
- d) Persons enrolled in ADAP shall recertify their eligibility every six months to continue receiving drugs through ADAP.
- 1) The Department will establish recertification procedures, as required by

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federal regulations and guidelines. Recertification applications, and any necessary new verifications, shall be received by the Department at least three business days prior to the expiration date of the client's current enrollment to avoid any interruption in service.

- 2) If the Department does not receive a recertification application at least three business days prior to the expiration date of the client's current enrollment, the client will be removed from ADAP and will be required to meet the eligibility requirements of subsections (a) through (c) of this Section in order to continue receiving drugs through ADAP.
 - 3) To avoid interruption in care, the Department will make reasonable attempts to notify recipients or their designees when an incomplete recertification application has been received.
- e) The Department will suspend a client's enrollment in ADAP under the following circumstances:
- 1) Failure to submit a completed initial or recertification application at least three business days prior to the expiration date of the client's current enrollment;
 - 2) Failure to use a minimum of one drug from any category of the ADAP formulary within 90 days after enrollment in ADAP; or
 - 3) The Department will send written notice of suspension within 30 days after the suspension, which may be appealed in accordance with subsection (k). The suspension will be lifted when the circumstances that initiated suspension have been rectified.
- f) The Department will permanently terminate a client's enrollment in ADAP if the client submits fraudulent application information. The Department will send written notice of termination with 30 days after the termination, which may be appealed in accordance with the provision of subsection (k).
- g) 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. Any cost control measures taken pursuant to this Section will be made only after a 90-day notice period to all applicants and providers.

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- h) All drugs provided under ADAP have been approved by the federal Food and Drug Administration. The Department will request the advice of the medical 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 ADAP:
- 1) Category I – Drugs for Anti-Retroviral Therapy;
 - 2) Category II – Drugs for Pneumocystis jirovecii (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.
- i) All prescriptions shall be filled by the Department's pharmacy contractors.
- j) 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).
- k) 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 recertification application filed pursuant to this Section within 30 business days after the date the Department receives the completed application, accompanied by all supporting verification documents that are provided by the applicant or on record with the Department. An applicant may appeal the Department's denial of an initial application, recertification application, or suspension or termination of benefits in accordance with Practice and Procedure in Administrative Hearings.

(Source: Amended by emergency rulemaking at 37 Ill. Reg. _____, effective March 18, 2013, for a maximum of 150 days)