

## 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	New
692.10	Amend
692.15	New
692.20	New
692.APPENDIX A	Repeal
692.APPENDIX B	Amend
- 4) Statutory 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]
- 5) A Complete Description of the Subjects and Issues Involved: This proposed rulemaking amends the rules for the Illinois AIDS Drug Assistance Program (ADAP) to reflect changes required in the Department's federal grant. Definitions were also added to better explain these changes. It also references new assistance programs in Illinois including Medicare Part D, Extra Help and Illinois Cares Rx. A new Section setting providing application requirements is being added. Appendix A is being repealed because federal poverty guidelines change annually.

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: Health Resources and Services Administration (HRSA) notice of grant award requirements and the establishment of various programs including Medicare Part D, Extra Help and Illinois Cares Rx. The Ryan White program has since been re-titled to the Treatment Extension Act.
- 7) Will this rulemaking replace any emergency rulemaking currently in effect? Yes; when adopted, will replace Ill. Adm. Code 692, 35 Ill. Reg. 16105

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- 8) Does this rulemaking contain an automatic repeal date? No
- 9) Does this rulemaking contain incorporations by reference? No
- 10) Are there any other proposed rulemakings pending on this Part? No
- 11) Statement of Statewide Policy Objectives: This rule will not affect any unit of local government that would require expenditure of local funds. The program is federally funded and supplemented by State GRF. All operations of the program are managed by the Department.
- 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., 5<sup>th</sup> floor  
Springfield, Illinois 62761
- 217/782-2043  
e-mail: [dph.rules@illinois.gov](mailto:dph.rules@illinois.gov)
- 13) Initial Regulatory Flexibility Analysis:
- A) Types of small businesses, small municipalities and not for profit corporations affected: None. This is a statewide program administered by the Department. Medications are through mail order and sent to the client's designated address.
- B) Reporting, bookkeeping or other procedures required for compliance: None outside of the Department's responsibility.
- C) Types of professional skills necessary for compliance: NA
- 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.

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The full text of the Proposed Amendments is identical to that of the Emergency Amendments for this rulemaking and begins in this issue of the *Illinois Register* on page 16105.

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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

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

EMERGENCY

692.15            Application Requirements

EMERGENCY

692.20            Referenced Materials

EMERGENCY

692.APPENDIX A    2000 Poverty Income Guidelines (Repealed)

EMERGENCY

692.APPENDIX B    Ryan White HIV/AIDS Treatment Extension Act of 2009~~CARE Act~~  
 Sliding Fee Scale

EMERGENCY

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.

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**Section 692.5 Definitions****EMERGENCY**

"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.

"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: Added by emergency rulemaking at 35 Ill. Reg. 16105, effective September 26, 2011, 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~~Section are paid for on behalf of low-income individuals with ~~acquired immunodeficiency syndrome~~Acquired Immunodeficiency Syndrome (AIDS) or human

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immunodeficiency virus ~~persons with the Human Immunodeficiency Virus~~ (HIV).

- a) Medical requirements. To qualify for services under this ~~Part~~Section, a person ~~shall have been~~must be enrolled in the AIDS Drug Assistance Program (ADAP) as of June 4, 1996, or:
- 1) ~~Apply make application with annual renewal to the Illinois Department of Public Health (Department) for acceptance for ADAP and comply with all recertification requirements, which occur every six months from the point of enrollment; and~~
  - 2) ~~Be~~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)3) ~~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%400% of the most recent Federal Poverty Level Guidelines published annually by the U.S. Department of Health and Human Services for the size of the household. (see Appendix A);~~
  - 2)4) ~~Applicants with 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 500% of the most recent Federal Poverty Level Guidelines for the size of the household. not be eligible for 80% or greater insurance coverage for drugs through another third party payer;~~
    - 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.

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- 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.
- 3)5) 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)6) Applicants shall not be eligible for payment for prescription drugs from any other governmental entity;; ~~and~~
- 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 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)7) 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)A) ~~The~~ the provision of Section 2-10 of the Illinois Public Aid Code stating that applicants for or recipients of public aid must meet ~~the such~~ such ~~durational~~ requirements for duration of as to residence contained in applicable Sections of the Public Aid Code shall not apply to this Part; and
- 2)B) ~~The~~ 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/AIDS Drug

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Assistance Program.

- d)b) Persons enrolled in the ADAP shall~~AIDS Drug Assistance Program must~~ reapply every six months~~annually in order~~ to continue receiving drugs through the ADAP~~Program~~.
- 1) Renewal applications shall~~must~~ 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~~by~~ the expiration date of the client's current enrollment.
  - 2) If the Department does not receive a renewal application at least three business~~is not received by the Department within 15~~ days prior to~~after~~ the expiration date of the client's current enrollment, the client will be removed from the ADAP~~Program~~ and will be required to meet the eligibility requirements of subsections (a)~~(1)~~ through (c)~~(7)~~ of this Section in order to continue receiving drugs through the ADAP~~Program~~.
- e)e) The Department shall~~may~~ suspend a client's enrollment in the ADAP~~AIDS Drug Assistance Program~~ under the following circumstances:
- 1) Submittal~~submittal~~ of fraudulent application information by an applicant or client;
  - 2) Failure~~failure~~ to submit a completed~~an~~ application at least three business days prior to the expiration date of the client's current enrollment~~by the due date; or~~
  - 3) Failure~~failure~~ to use a minimum of one drug from any category of the ADAP formulary within 90 days after enrollment to the ADAP~~utilize the Program for a six-month period.~~
- f)e) Subject to the availability of funds, the Department may implement cost control measures at any time to ensure the long-term sustainability of the programs~~such as client benefit maximums or limitations on new enrollments.~~
- g)e) All drugs provided under the ADAP~~AIDS Drug Assistance Program~~ have been approved by the federal Food and Drug Administration. The following categories of drugs may be covered under the AIDS Drug Assistance Program.~~The~~

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Department ~~will request, with~~ the advice of the medical issues subcommittee of the ~~Title II~~ Ryan White ADAP Medical Issues Advisory Board when necessary to assist with determining ~~AIDS Advisory Council, will determine~~ 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) ~~for 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)A) All prescriptions ~~shall~~must be filled by the Department's pharmacy contractors.

i)g) The Department may require participants to pay a copayment for prescriptions received. If a copayment is charged, it ~~shall~~must not exceed the sliding fee structure specified in ~~Part B~~Title II of the Ryan White HIV/AIDS Treatment Extension Act of 2009~~CARE Act~~ (see Appendix B).

j)h) The Department will make a disposition and issue a written decision on an application filed pursuant to this Section within 30 business~~15~~ days ~~after~~from 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~~15~~ days ~~after~~from the date the Department receives the completed application. An individual may appeal the Department's denial of his/her application. ~~Such appeal shall be~~ in accordance with ~~the Department's Rules of~~ Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100).

(Source: Amended by emergency rulemaking at 35 Ill. Reg. 16105, effective September 26, 2011, for a maximum of 150 days)

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**Section 692.15 Application Requirements**  
**EMERGENCY**

Applications for participation in the ADAP shall be submitted on forms provided by the Department. Information requested on the application will include, but not be limited to:

- a) Patient information, including marital status, race/ethnicity, pregnancy information, and risk factors;
- b) Residency information, including mailing address and prescription address, if different from mailing address;
- c) Demographic and income information on household members who qualify as legal dependants to the ADAP applicant, and who may also contribute to the household income, which would affect the federal poverty level for the applicant as defined by the ADAP's federal partner, the United States Health Resources and Services Administration (HRSA);
- d) Applicant's income information, including, but not limited to:
  - 1) Gross monthly income, from sources such as wages, unemployment compensation, Social Security, Social Security Disability, veterans' pension, veterans' disability, private disability, worker's compensation, temporary assistance for needy families, general assistance, retirement income, child support, alimony or other spousal support, or any/or all other sources of income provided by the applicant;
  - 2) Documentation of income from paycheck stubs, benefit statement, award letter, court order, federal tax return, or other document provided by the applicant;
- e) Physician information, including, but not limited to, HIV physician, prescribing physician if HIV physician does not prescribe HIV medication, and ADAP liaison (individual to contact on applicant's behalf);
- f) Insurance/benefit information, including, but not limited to, prescription insurance, Medicare, Medicare Part D, Medicare Supplement, Medicaid, Illinois Cares Rx, and veterans' benefits;

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- g) Clinical information, including, but not limited to, current diagnosis, initial diagnosis, most recent CD4 count, and most recent viral blood count; and
- h) Client verification and authorization to release confidential information.

(Source: Added by emergency rulemaking at 35 Ill. Reg. 16105, effective September 26, 2011, for a maximum of 150 days)

**Section 692.20 Referenced Materials****EMERGENCY**

The following materials are 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)

(Source: Added by emergency rulemaking at 35 Ill. Reg. 16105, effective September 26, 2011, for a maximum of 150 days)

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**Section 692.APPENDIX A 2000 Poverty Income Guidelines (Repealed)  
EMERGENCY**

<del>Size of Family Unit</del>	<del>Poverty Guideline</del>	<del>Maximum Gross Annual Income ADAP Eligibility</del>
<del>1</del>	<del>\$ 8,350</del>	<del>\$ 33,400</del>
<del>2</del>	<del>11,250</del>	<del>45,000</del>
<del>3</del>	<del>14,150</del>	<del>56,600</del>
<del>4</del>	<del>17,050</del>	<del>68,200</del>
<del>5</del>	<del>19,950</del>	<del>79,800</del>
<del>6</del>	<del>22,850</del>	<del>91,400</del>
<del>7</del>	<del>25,750</del>	<del>103,000</del>
<del>8</del>	<del>28,650</del>	<del>114,600</del>

~~For family units with more than 8 members, add \$2,900 for each additional member.~~

(Source: Repealed by emergency rulemaking at 35 Ill. Reg. 16105, effective September 26, 2011, for a maximum of 150 days)

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**Section 692.APPENDIX B Ryan White HIV/AIDS Treatment Extension Act of 2009~~CARE Act~~ Sliding Fee Scale**

~~CARE Act~~ Sliding Fee Scale

Individual/Family Annual Gross Income	Total Allowable Annual Charges
Equal to or below the official poverty line	No charges permitted
101 to 200 percent of the official poverty line	5 percent or less of gross income level
201 to 300 percent of the official poverty line	7 percent or less of gross income level
more than 300 percent of the official poverty line	10 percent or less of gross income level

(Source: Amended by emergency rulemaking at 35 Ill. Reg. 16105, effective September 26, 2011, for a maximum of 150 days)