

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) Section Numbers: Emergency Action:

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) Effective Date of Rules:
- 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: This emergency rule will not expire before the end of the 150-day period.
- 7) Date filed with the Index Department:
- 8) A copy of the adopted amendments, 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 Illinois Department of Public Health administers the AIDS Drug Assistance Program (ADAP), which currently serves on average 4,235 clients each month, accessing an average of 141,100 prescriptions annually. The program is funded through two primary funding streams; federal funding through the Ryan White Care Act (The legislation was first enacted in 1990) administered through the United States Health Resources and Services Administration (HRSA); and State general revenue.

As of June 1, 2011, ADAP provides 81 different drugs on its formulary, including all anti-retroviral therapies approved by the U.S. Food and Drug Administration. Clients have a benefit cap of \$2,000 per month, except for 3 drugs in Category V, which is sufficient to

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support triple and quadruple combination therapies. These drug combinations have been successful in treating persons with HIV infection; including the treatment of opportunistic infections frequently associated with HIV; drug treatment adherence; and have been credited with dramatic prolonging of life for individuals infected with HIV.

Currently the ADAP program is operating out of compliance of the Health Resources and Service Administration (HRSA) grant requirements. Grant requirements state that ADAP enrollment needs to be conducted at six-month intervals, and the current rules require 12-month intervals. To be compliant with the multi-million dollar federal grant and not face potential financial penalty, HRSA is requiring the Department to abide by their grant requirements. If the State does not comply, funding could be withheld, forcing the program not to fill life-saving drug prescriptions for thousands of Illinois residents who are HIV infected. In addition, the discontinuation of services would have an impact on two large contracts, including the Department's dispensing pharmacy and wholesaler. The current HRSA award to the Department is approximately \$36 million with an additional \$18 million of General Revenue Funds (GRF) to supplement the cost of the ADAP program.

Section 5-45 of the Illinois Administrative Procedure Act (IAPA) defines an "emergency" as "the existence of any situation that any agency finds reasonably constitutes a threat to the public interest, safety, or welfare." In addition, the situation "requires adoption of a rule upon fewer days than is required" under the regular rulemaking provisions of the IAPA. This situation constitutes an emergency because of the threat to the public interest, safety and welfare indicated by the potential loss of federal funding to provide life-prolonging medication to low-income individuals who have been diagnosed with AIDS/HIV. Since the majority of the funding for this program comes from federal dollars, it is crucial for the Department to make sure that its rules comply with the federal requirements that ensure continuation of the funding.

The Department has been informed in federal fiscal year 2011 through notice of grant award that ADAP applicants are to be recertified every six months. The United States Health Resources and Services Administration has informed the Department that failure to comply with the six-month recertification policy would result in federal penalties, including loss of federal funding or repayment of previously awarded funds. The penalties would involve placing the program on "administrative draw down restrictions," requiring reimbursement to the federal payer with GRF for those agencies which received federal funding and were not recertified in appropriate time parameters dictated by agreements.

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In the absence of these emergency amendments, the Department will not receive funding for the program, and could even face repaying funds that it has already received, resulting in the discontinuation of services to the Department's ADAP clients. The prescription medications obtained through ADAP provide a vital public health service and essential medical care to individuals who would not otherwise be able to obtain these medications.

10) A complete Description of the Subjects and Issues Involved:

This proposal is to amend 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. The rules also reference new assistance programs in Illinois, including Medicare Part D, Extra Help, and Illinois Cares Rx. The Department is repealing Appendix A as the guidelines for federal poverty level change annually.

11) Are there any Proposed amendments to this Part pending? No

12) 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.

13) Information and questions regarding these rules shall be directed to:

Susan Meister
Administrative Rules Coordinator
Department of Public Health
535 W. Jefferson St., 5th Floor
(217)782-2043
dph.rules@illinois.gov

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

692.10 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

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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 [Public Law 111-87] ~~Title II of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 [42 USC 300ff]~~, 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. _____, effective _____, 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.

“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. _____, effective _____, 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 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. ~~for those applicants who have active prescription coverage at the time of enrollment;~~
 - 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

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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 spend down 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 ~~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 Assistance Program.~~
- d)b) Persons enrolled in the ADAP shall ~~AIDS Drug Assistance Program~~ must reapply

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every six months ~~annually in order~~ to continue receiving drugs through the ADAP Program.

- 1) Renewal applications shall be complete, with all fields on the application filled out, shall include all required support documentation and shall must 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 is not received by the Department- at least three business 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)~~(4)~~ 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 utilize a minimum of one drug from any category of the ADAP formulary within 90 days after enrollment to the ADAP the Program for a six month period.

~~f)~~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 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 Department will request, ~~with~~ the advice of the medical issues subcommittee of the ~~Title II Part B~~ 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

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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 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.

~~h) f)~~ 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. _____, effective _____, for a maximum of 150 days)

Section 692.15 Application Requirements
EMERGENCY

Applications for participation in the ADAP shall be submitted on forms provided by the

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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;
- 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.

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(Source: Added by emergency rulemaking at 35 Ill. Reg. _____, effective _____, 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 36 Ill. Reg. _____, effective _____, for a maximum of 150 days)

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

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

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8 28,650 114,600

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

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

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

~~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. _____, effective _____, for a maximum of 150 days)