

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF ADOPTED AMENDMENTS

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

<u>Section Numbers:</u>	<u>Adopted Action:</u>
692.5	New
692.6	New
692.10	Amended
692.15	New
692.16	New
692.APPENDIX A	Amended
692.APPENDIX B	Amended
- 4) Statutory Authority: Ryan White HIV/AIDS Treatment Extension Act of 2009 (P.L. 111-87) and Section 315 of the Civil Administrative Code of Illinois [20 ILCS 2310/315]
- 5) Effective Date of Rulemaking: February 22, 2012
- 6) Does this rulemaking contain an automatic repeal date? No
- 7) Does this rulemaking contain incorporations by reference? No
- 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) Notice of Proposed Amendments Published in Illinois Register: October 7, 2011; 35 Ill. Reg. 15976
- 10) Has JCAR issued a Statement of Objection to this rulemaking? No
- 11) Differences between proposal and final version:

The following changes were made in response to comments received during the first notice or public comment period:

1. In Section 692.5, a definition of "Prescription insurance" was added.
2. In Section 692.10(a), "Medical requirements" was changed to "Eligibility requirements".

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3. In Section 692.10(b), a new subsection (2)(C) was added.
4. In Section 692.10(b)(4), the following was added after "entity": "except Medicare, Medicaid (if spend-down is met) or Illinois Cares Rx".
5. In Section 692.10(b)(5), the following was added after "shall": "enroll in Medicare Part D and".
6. In Section 692.10(b)(7), "or denial" was deleted in the second sentence.
7. In Section 692.15(c), "(name, date of birth, relationship)" was added after "Demographic".

The following changes were made in response to comments and suggestions of JCAR:

1. In Section 692.10(a)(2), "through submission of a CD4 and...recertification date:" was changed to "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".
2. In Section 692.10(b)(2), "insurance" was deleted; "of the most" was changed to "FPL".
3. In Section 692.10(b)(2)(C), "renewals" was changed to "recertifications".
4. In Section 692.10(b)(~~4~~6), the existing label and text were stricken and the new text was deleted.
5. In Section 692.10(b)(5 (new (4))), the text in the second and third lines was deleted and "D and provide information on the Part D coverage plan" was added.
6. In Section 692.10(b)(6 (new (5))), the text in the second and third lines was deleted and "provide information on Medigap plan and coverage" was added.
7. In Section 692.10(b)(7(new (6))), the text in the second, third, and fourth lines was deleted and "applicant must enroll and provide information on coverage" was added.

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8. In Section 692.10(d), "recertify their eligibility" was added after "shall" and "reapply" was stricken.
9. Section 692.10(d)(1) was amended as follows:
"The Department will establish recertification procedures, as required by federal regulations and guidelines. Recertification applications, and any necessary new verifications. Renewal applications must be shall be received by the Department at least three business days prior to by the expiration date of the client's current enrollment to avoid any interruption in service."
10. In Section 692.10(d)(2), "renewal" in the first line was stricken and "recertification" was added.
11. A new subsection was added at Section 692.10(d)(3).
12. In Section 692.10(e)(1), existing text was stricken and new text was deleted.
13. In Section 692.10(e)(2 (new (1))), "initial or recertification" was added after "completed".
14. New subsections were added at Section 692.10(e)(3) and (f).
15. A new sentence was added at the end of Section 692.10 (new g) after "enrollments".
16. In Section 692.10(new (k)), "renewal" was stricken and "recertification" was added; after "application", the following was added: ", accompanied by all supporting verification documents that are provided by the applicant or on record with the Department".
17. In Section 692.10(new (k)), after "application", ", recertification application, or suspension or termination of benefits" was added.
18. In Section 692.15(d)(2), "or available to the Department" was added after "applicant".
19. In Section 692.15(g), "blood" was changed to "load".
20. A new Section 692.16 was added.

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21. Appendix A was amended to add the 2012 Poverty Income Guidelines.

In addition, various typographical, grammatical, and form changes were made in response to the comments from JCAR.

- 12) Have all the changes agreed upon by the agency and JCAR been made as indicated in the agreements issued by JCAR? Yes
- 13) Will this rulemaking replace any emergency rulemaking currently in effect? Yes
- 14) Are there any amendments pending on this Part? No
- 15) Summary and Purpose of Rulemaking: Due to expanded growth of the AIDS Drug Assistance Program (ADAP) operated by the Illinois Department of Public Health, and the fiscal limitations in funding streams (Federal and State), the program was required to adjust eligibility criteria. The rulemaking process was required to ensure current eligibility rules were in line with new policies drafted by the Department. The rulemaking includes new definitions to better explain these changes and references to new assistance programs in Illinois, including Medicare Part D, Extra Help, and Illinois Cares Rx. A new Section providing application requirements is added. Referenced materials are also added. Appendix A was amended during the first notice period to include the 2011 federal poverty guidelines and has since been updated to the 2012 guidelines. A new Section on non-discrimination has been added, and references to "renewal" have been replaced with "recertification". Changes made during second notice make the application and recertification process easier and clarify provisions regarding suspension or termination from the program.
- 16) Information and questions regarding these adopted amendments shall be directed to:

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Department of Public Health
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Springfield, Illinois 62761

217/785-9128
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The full text of the Adopted 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
692.6	Referenced Materials
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	20122000 Poverty Income Guidelines
692.APPENDIX B	Ryan White HIV/AIDS Treatment Extension Act of 2009 CARE Act 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.

[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 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: Added at 36 Ill. Reg. 3909, effective February 22, 212)

Section 692.6 Referenced Materials

The following materials are referenced in this Part:

- a) Illinois Statutes
 - 1) Civil Administrative Code of Illinois [20 ILCS 2310]

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- 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 at 36 Ill. Reg. 3909, effective February 22, 212)

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~~Section are paid for on behalf of low-income individuals with ~~acquired immunodeficiency syndrome~~Acquired Immunodeficiency Syndrome (AIDS) or ~~human immunodeficiency virus~~persons with the Human Immunodeficiency Virus (HIV).

- a) Eligibility 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 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

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- 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% FPL 400% 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. (Seese 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% FPL for the size of the household. not be eligible for 80% or greater insurance coverage for drugs through another third party payor;
- 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 failure to reapply on time, then the applicant will be assessed using the 300% FPL eligibility limit.
- 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).;

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- 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.
- 6) ~~not be eligible for payment for prescription drugs from any other governmental entity; and~~
- 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 Assistance Program.~~
- d)b) Persons enrolled in ~~the ADAP~~ shall recertify their eligibility AIDS Drug Assistance Program ~~must reapply every six months annually in order~~ to continue receiving drugs through ~~the ADAP~~ Program.
- 1) The Department will establish recertification procedures, as required by federal regulations and guidelines. Recertification applications, and any necessary new verifications, Renewal applications must be shall be received by the Department at least three business days prior to ~~by~~ the expiration date of the client's current enrollment to avoid any interruption in service.
- 2) If the Department does not receive a recertification renewal application at least three business ~~is not received by the Department within 15~~ days prior

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~~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~~.

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)e) The Department ~~will~~may suspend a client's enrollment in ~~the ADAP AIDS Drug Assistance Program~~ under the following circumstances:

1) ~~submittal of fraudulent application information by an applicant or client;~~

12) ~~Failure~~failure to submit a completed initial or recertification an application at least three business days prior to the expiration date of the client's ~~current enrollment~~by the due date;

23) ~~Failure~~failure to use a minimum of one drug from any category of the ADAP formulary within 90 days after enrollment in ADAP; or utilize the Program for a six month period.

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)d) 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. Any cost control measures taken pursuant to this Section will be made only after a 90-day notice period to all applicants and providers.

h)e) All drugs provided under ~~the ADAP AIDS Drug Assistance Program~~ have been

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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~~ 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 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.

~~i)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).

~~k)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 recertification~~renewal~~ application filed pursuant to this Section within ~~30 business~~15 days ~~after~~from 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~~individual~~ may appeal the Department's denial of an initial~~his/her~~ application, recertification application, or suspension or termination of benefits. ~~Such appeal shall be~~ in accordance with ~~the Department's Rules of Practice and Procedure in Administrative Hearings~~ (~~77 Ill. Adm. Code 100~~).

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(Source: Amended at 36 Ill. Reg. 3909, effective February 22, 212)

Section 692.15 Application Requirements

Applications for participation in 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 (name, date of birth, relationship) 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 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, workers' 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 documentation provided by the applicant or available to the Department;
- e) Medical provider 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);

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- 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 load count; and
- h) Client verification and authorization to release confidential information.

(Source: Added at 36 Ill. Reg. 3909, effective February 22, 212)

Section 692.16 Non-Discrimination

The Department will ensure that no individual participating in any program or activity of ADAP will be discriminated against because of race, color, religious belief, political affiliation, sex, sexual orientation, national origin or handicap. Pursuant to the requirements of State and federal law, the Department will make reasonable accommodations for individuals with disabilities.

(Source: Added at 36 Ill. Reg. 3909, effective February 22, 212)

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Section 692.APPENDIX A ~~2012~~2000 Poverty Income Guidelines**2012 Health and Human Services Poverty Guidelines**

<u>Persons in Family</u>	<u>Poverty Guideline</u>	<u>Maximum Gross Annual Income ADAP 300% Eligibility</u>
<u>1</u>	<u>\$11,170</u>	<u>\$ 33,510</u>
<u>2</u>	<u>\$15,130</u>	<u>\$ 45,390</u>
<u>3</u>	<u>\$19,090</u>	<u>\$ 57,270</u>
<u>4</u>	<u>\$23,050</u>	<u>\$ 69,030</u>
<u>5</u>	<u>\$27,010</u>	<u>\$ 81,030</u>
<u>6</u>	<u>\$30,970</u>	<u>\$ 92,910</u>
<u>7</u>	<u>\$34,930</u>	<u>\$104,790</u>
<u>8</u>	<u>\$38,890</u>	<u>\$116,670</u>
<u>For additional persons, add</u>	<u>\$ 3,960</u>	<u>\$ 11,880</u>

NOTE: See 77 Fed. Reg. 4034-4035 (January 26, 2012).

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

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

(Source: Amended at 36 Ill. Reg. 3909, effective February 22, 2012)

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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 at 36 Ill. Reg. 3909, effective February 22, 2012)