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DEPARTMENT OF PUBLIC HEALTH

DRAFT NOTICE OF ADOPTED AMENDMENTS 1-30-12

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

PART 692
AIDS DRUG ASSISTANCE PROGRAM

Section

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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 amendments at 35 Ill. Reg. 16105, effective September 26, 2011, for a maximum of 150 days; amended at 36 Ill. Reg. _____, effective _____.

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Section 692.5 Definitions

“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.

“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. _____, effective _____)

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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]
 - 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. _____, 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 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

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2) Be be-diagnosed as having AIDS or HIV; 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. 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) Applicant 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.

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) An applicant who was enrolled in ADAP on July 1, 2011, in the 301-500% income bracket of the federal poverty level shall be grandfathered into ADAP on a go-forward basis, as long as the applicant's renewals recertifications are complete and submitted on

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time and they do not exceed the 500% of federal poverty level. If an applicant within this cohort is closed from the program due to failure to reapply on time, then the applicant will be assessed at the lower 300% of the federal income level.

- 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, except Medicare, Medicaid (if spend down is met) or Illinois Cares Rx; and-
- 4) 5) If eligible for Medicare Part D, the applicant shall enroll in Medicare Part D and provide information on the Part D coverage plan; a clear copy of both the front and back of the Medicare Part D insurance card.;
- 5) 6) If enrolled in a Medicare Supplement plan (Medigap), the applicant shall provide information on Medigap plan and coverage; clear copy of both the front and back of the Medicare Supplement insurance card.;
- 6) 7) If eligible for federal Extra Help or Illinois Cares Rx Plan (ICRx), the applicant must enroll and provide information on coverage. 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 applicant 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.

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d)b) Persons enrolled in the ADAP shall ~~AIDS Drug Assistance Program~~ must reapply recertify their eligibility every six months ~~annually in order~~ to continue receiving drugs through the ADAP Program.

1) The Department will establish recertification procedures, consistent with federal requirements. Recertification applications, and any necessary new verifications, must shall 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 to avoid any interruption in service.

2) If the Department does not receive a renewal recertification 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.

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;~~

1)2) Failure failure to submit a completed an initial or recertification application at least three business days prior to the expiration date of the client's current enrollment by the due date; or

2)3) Failure failure to use utilize a minimum of one drug from any category of the ADAP formulary within 90 days after enrollment in the ADAP 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) below. The suspension will be lifted when the

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circumstances that initiated suspension have been rectified.

f) The Department will permanently terminate a client's enrollment in the ADAP under the following circumstances: 1) ~~Submittal of if the client submits fraudulent application information, by an applicant or client;~~ The Department will send written notice of termination within 30 days of the termination, which may be appealed in accordance with the provisions of subsection k below.

~~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 pursuant to this Section will be only after a 90-day notice period to all applicants and providers. ~~such as client benefit maximums or limitations on new enrollments.~~

~~e-h)~~ 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 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.

~~i)~~ All prescriptions shall ~~must~~ be filled by the Department's pharmacy contractors.

~~j)~~ The Department may require participants to pay a copayment for prescriptions

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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).-

- ~~h)~~k) 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-recertification application filed pursuant to this Section within 30 business ~~15~~ days ~~after from~~ the date the Department receives the 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 his/her an applicant's initial 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).

(Source: Amended at 36 Ill. Reg. _____, effective _____)

Section 692.15 Application Requirements

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 (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 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'

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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 documentation provided by the applicant or available to the Department;
- e) Medical provider 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 load blood count; and
- h) Client verification and authorization to release confidential information.

(Source: Added at 36 Ill. Reg. _____, effective _____)

Section 692.16 Non-discrimination.

The Department will ensure that no individual participating in any program or activity of the 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 the State and federal law, the Department will make reasonable accommodations for individuals with disabilities.

(Source: Added at 36 Ill. Reg. _____, effective _____)

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Section 692.APPENDIX A 2011 ~~2000~~ Poverty Income Guidelines

<u>2011 Health and Human Services Poverty Guidelines</u>		
<u>Persons in Family</u>	<u>Poverty Guideline</u>	<u>Maximum Gross Annual Income ADAP 300% Eligibility</u>
<u>1</u>	<u>\$10,890</u>	<u>\$32,670</u>
<u>2</u>	<u>14,710</u>	<u>44,130</u>
<u>3</u>	<u>18,530</u>	<u>55,590</u>
<u>4</u>	<u>22,350</u>	<u>67,050</u>
<u>5</u>	<u>26,170</u>	<u>78,510</u>
<u>6</u>	<u>29,990</u>	<u>89,970</u>
<u>7</u>	<u>33,810</u>	<u>101,430</u>
<u>8</u>	<u>37,630</u>	<u>112,890</u>
For additional persons, add	<u>3,820</u>	<u>11,460</u>
<u>Source: Federal Register, Vol. 76, No. 13, January 20, 2011, pp. 3637-3638</u>		

Size of Family Unit	Poverty Guideline	Maximum Gross Annual Income ADAP Eligibility
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
8	28,650	114,600

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

(Source: Amended at 36 Ill. Reg. _____, effective _____)

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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. _____, effective _____)