

**Department of State
Division of Publications**

312 Rosa L. Parks Avenue, 8th Floor Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Fax: 615-741-5133
Email: register.information@tn.gov

For Department of State Use Only

Sequence Number: 01-02-12
Rule ID(s): 5123
File Date: 01/03/2012
Effective Date: 06/30/2012

Proposed Rule(s) Filing Form

Proposed rules are submitted pursuant to T.C.A. §§ 4-5-202, 4-5-207 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within sixty (60) days of the first day of the month subsequent to the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by twenty-five (25) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of twenty-five (25) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.

Agency/Board/Commission:	Department of Health
Division:	Communicable and Environmental Disease Services
Contact Person:	Carolyn Wester, M.D.
Address:	425 5 th Avenue North, 1 st Floor, Nashville TN
Zip:	37243
Phone:	615-741-7247
Email:	Carolyn.Wester@tn.gov

Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1200-14-02	HIV Drug Reimbursement (HDR) Program Rules
Rule Number	Rule Title
1200-14-02-.01	Definitions
1200-14-02-.02	Purpose and Administration of the HDR Program
1200-14-02-.03	Program Limited to Available Funds
1200-14-02-.04	Eligibility Criteria
1200-14-02-.05	Deeming of Income and Resources
1200-14-02-.06	Certification of Coverage by Program
1200-14-02-.07	Confidentiality of Records

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

1200-14-02 HIV Drug Reimbursement (HDR) Program Rules are amended by deleting the chapter in its entirety and changing the name to AIDS Drug Assistance Program Rules and substituting instead the following, so that as amended, rules chapter 1200-14-02 shall read:

AIDS Drug Assistance Program Rules

1200-12-02-.01 Definitions

- (1) For the purpose of these regulations the terms used herein are defined as follows:
 - (a) "ADAP" means the AIDS Drug Assistance Program, the federal earmark in the Ryan White Part B grant providing funding for HIV Clients' medications, which encompasses HDAP and IAP.
 - (b) "AIDS" means Acquired Immune Deficiency Syndrome or Acquired Immunodeficiency Syndrome.
 - (c) "Certification" means the determination that an applicant meets the eligibility criteria to receive assistance through the Ryan White Program.
 - (d) "Client" means a person enrolled in the Ryan White Program.
 - (e) "Department" means the Tennessee Department of Health.
 - (f) "FDA" means the U.S. Food and Drug Administration.
 - (g) "Formulary" means the HDAP Formulary, which lists the FDA approved medications provided by Tennessee's HDAP Program.
 - (h) "HDAP" means the HIV Drug Assistance Program, a program through which the Department provides Formulary medications to Clients.
 - (i) "HIV" means Human Immunodeficiency Virus.
 - (j) "IAP" means Insurance Assistance Program, a program through which the Department provides assistance paying health insurance premiums, co-payments, and/or deductibles for eligible Clients.
 - (k) "Priority Group" means those eligible for temporary emergency access to HDAP or IAP services if there is a waiting list.
 - (l) "Program Director" means the Department employee responsible for the overall management of grants and programs in the HIV/AIDS/STD Section of the Department.
 - (m) "Provider" means a health care professional with prescriptive authority, licensed pursuant to Title 63 of the Tennessee Code.
 - (n) "Ryan White Program" means the Departmental program that receives federal Ryan White Part B funding and provides medical services, medications, and support services to eligible individuals.
 - (o) "TennCare" means Tennessee's State Medicaid Program.

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.

1200-14-02-.02 Purpose and Administration of ADAP Funds

(1) HDAP

Through HDAP, the Department shall:

- (a) Provide applications and instructional forms regarding eligibility criteria, the Formulary, and other guidelines for participation;
- (b) Determine which medications shall be included in the Formulary;
- (c) Purchase Formulary medications for Clients;
- (d) Contract licensed pharmacists to Provide Formulary medications to Clients pursuant to prescriptions by providers; and
- (e) Coordinate with TennCare to ensure that Clients do not receive benefits from both programs simultaneously.

(2) IAP

Through IAP, the Department shall:

- (a) Provide applications and instructional forms regarding eligibility criteria, the Formulary, and other guidelines for participation;
- (b) Provide assistance paying health insurance premiums, co-payments, and/or deductibles for eligible Clients.

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.

1200-14-02-.03 Eligibility Criteria

- (1) To qualify for Ryan White Program services, an applicant must submit a completed and signed Ryan White Program application including evidence that applicant meets the following eligibility requirements:
 - (a) Is a resident of Tennessee;
 - (b) Meets the generally accepted medical criteria for HIV disease;
 - (c) Has an annual income of less than 300% of the current year's federal poverty level;
 - (d) Has no more than \$8,000.00 in liquid assets; and
 - (e) For ADAP applicants, presents certification that applicant has no other source of third party reimbursement for prescription drugs.
- (2) For purposes of establishing income and assets the following shall apply:
 - (a) For applicants 18 years and older, only the income and assets of the applicant and the applicant's legal spouse with whom the applicant resides will be considered.
 - (b) For applicants less than 18 years of age, the income and assets of the applicant and the legal parent or parents with whom the applicant resides will be considered. Income and assets of step-parents and legal guardians shall not be considered.
- (3) In order to continue to receive any Ryan White Program services, a Client must submit the following every six (6) months:
 - (a) Confirmation that the Client continues to meet the eligibility criteria; and

- (b) A completed and signed recertification application.

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.

1200-14-02-.04 Program Limited to Available Funds

- (1) The availability of funds limits the number of Clients receiving ADAP services. The Department shall cease approval of applications if funding is insufficient to sustain additional recipients.
- (2) Current Clients shall have priority for funding.
- (3) Eligible applicants who are denied ADAP enrollment due to a funding shortage shall be placed on a waiting list managed by the Ryan White Program.
- (4) Individuals on the ADAP waiting list in one of the following Priority Groups shall be provided with temporary emergency ADAP services as follows:
 - (a) Pregnant women shall be eligible for ADAP services during pregnancy and up to 90 days post partum; and
 - (b) Infants up to one year of age shall be eligible for ADAP services for up to 180 days of coverage.

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.

1200-14-02-.05 Certification of Coverage by Program

- (1) The Department will notify applicants whether certification of coverage has been awarded. Applicants for whom coverage is certified are not guaranteed ADAP services beyond the federal fiscal year of the current grant.

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.

1200-14-02-.06 Reconsideration of Denial

- (1) Applicants denied or removed from participation in HDAP or IAP may request reconsideration.
 - (a) The applicant must request reconsideration in writing, directed to the Program Director, within twenty one (21) calendar days of denial or removal. The Program Director will issue a reconsidered decision in writing within fourteen (14) days of the request for reconsideration. The Program Director's review is limited to a determination of whether or not the applicant meets eligibility criteria. The decision of the Program Director is final.

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.

1200-14-2-.07 Confidentiality of Records.

All applicant or recipient identifying information or records of the ADAP program shall be considered confidential as required by the federal legislation authorizing funding assistance to the program: Such information or records shall not be disclosed by the program except for those purposes for which a signed release is provided by the person served. All correspondence containing the identity of program applicants or recipients shall be sealed and marked "CONFIDENTIAL".

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.

* If a roll-call vote was necessary, the vote by the Agency on these rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
NA					

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the Commissioner of the Department of Health on 11/08/2011, and is in compliance with the provisions of T.C.A. § 4-5-222. The Secretary of State is hereby instructed that, in the absence of a petition for proposed rules being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of sixty (60) days of the first day of the month subsequent to the filing of the proposed rule with the Secretary of State.



Date: 11/14/11

Signature: Mary Kennedy

Name of Officer: Mary Kennedy

Deputy General Counsel

Title of Officer: Tennessee Department of Health

Subscribed and sworn to before me on: Nov. 14, 2011

Notary Public Signature: Sue B. Hunt

My commission expires on: July 8, 2013

All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

RE Cooper Jr

Robert E. Cooper, Jr.
Attorney General and Reporter

12-19-11
Date

Department of State Use Only

RECEIVED
2011 DEC 20 PM 12:40
SECRETARY OF STATE
PUBLICATIONS

Filed with the Department of State on: 01-03-12

Effective on: 06/30/2012

Tre Hargett

Tre Hargett
Secretary of State

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

These rule amendments do not affect small businesses.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

These rule amendments are not expected to have an impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to TCA 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

This rule provides applicants with clear guidance on the criteria for obtaining insurance assistance or drug assistance for the treatment of HIV/AIDS. It sets forth the criteria for acceptance into the program and, in the event that the program should exhaust available funds before the end of its fiscal year, makes provision for certain priority patients to obtain emergency assistance, and sets the guideline for a waiting list. It repeals a provision for drug assistance which was limited to a specific and outdated formulary, and gives enough latitude for the use of drugs which may become available in the future.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

None

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

The persons most affected by this rule are persons living with HIV who would qualify for ADAP services and those agencies who provide ADAP services. There has been considerable discussion with affected individuals and with agencies. There has been no disagreement voiced.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

None.

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

No impact

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Carolyn Wester, MD, Jeanece Seals

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Jeanece Seals, Mary Kennedy, Deputy General Counsel

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Mary Kennedy, Deputy General Counsel, TDOH, 3rd Floor, Cordell Hull Building, 425 5th Avenue North, Nashville TN 37243, (615) 253-4878. mary.kennedy@tn.gov; Jeanece Seals, Director, HIV/AIDS/STD Section, TDOH, 4th Floor, Cordell Hull Building, 425 5th Avenue, North, Nashville TN 37247 615(532-7188) jeanece.seals@tn.gov.

- (I) Any additional information relevant to the rule proposed for continuation that the committee requests.

None at this time.

RULES
OF
THE DEPARTMENT OF HEALTH
AIDS PROGRAM DIVISION

CHAPTER 1200-14-2
HIV DRUG REIMBURSEMENT (HDR) PROGRAM RULES
AIDS DRUG ASSISTANCE PROGRAM RULES

TABLE OF CONTENTS

1200-14-2-.01	Definitions		
1200-14-2-.02	Purpose and Administration of the HDR <u>Program ADAP Funds</u>	1200-14-2-.05	<u>Deeming of Income and Resources</u> <u>Certification of Coverage by Program</u>
1200-14-2-.03	Program Limited to Available Funds <u>Eligibility Criteria</u>	1200-14-2-.06	<u>Certification of Coverage by Program</u> <u>Reconsideration of Denial</u>
1200-14-2-.04	<u>Eligibility Criteria</u> <u>Program Limited to</u> <u>Available Funds</u>	1200-14-2-.07	Confidentiality of Records

~~1200-14-2-.01 DEFINITIONS.~~

- (1) — ~~For the purpose of these regulations the terms used herein are defined as follows:~~
- (a) — ~~ALPHA INTERFERON — An FDA approved drug also known by the brand names *Intron-A* or *Roferon*.~~
 - (b) — ~~AEROSOLIZED PENTAMIDINE — A formulation of the FDA approved drug Pentamidine isethionate, also known by the brand name *Nebupent*.~~
 - (c) — ~~AIDS — Acquired Immune Deficiency Syndrome or Acquired Immunodeficiency Syndrome.~~
 - (d) — ~~AZT — The drug Azidothymidine, also known by the generic name “zidovudine” and the brand name *Retrovir*.~~
 - (e) — ~~CERTIFICATION — The determination that an eligible applicant shall become an approved recipient of the HDR program.~~
 - (f) — ~~COMMISSIONER — The Commissioner of the Tennessee Department of Health or his designee.~~
 - (g) — ~~DEPARTMENT — The Tennessee Department of Health~~
 - (h) — ~~ELIGIBLE APPLICANT — An applicant who has an income that does not exceed the maximum monthly income level established by the program (reference paragraph 3, section 1200-14-2-.02), has liquid resources that do not exceed \$8,000 and who has no other source to pay for the drug(s) prescribed under the program.~~
 - (i) — ~~FDA — The U.S. Food and Drug Administration.~~
 - (j) — ~~HDR PROGRAM — HIV Drug Reimbursement Program.~~
 - (k) — ~~HDR PROGRAM APPLICATION — A form available from the Tennessee Department of Health that provides for : 1) a physician’s declaration of medical appropriateness for an applicant to receive the drug and the physician’s intent to medically follow the applicant; and 2) an applicant’s declaration that they meet all eligibility criteria to participate in the HDR program.~~
 - (l) — ~~HIV — Human Immunodeficiency Virus.~~

(Rule 1200-14-2-.01, continued)

~~(m) — HIV DISEASE — The state of being infected with the Human Immunodeficiency Virus.~~

~~(n) — HIV DRUG REIMBURSEMENT PROGRAM — A program of the Tennessee Department of Health, Bureau of Health Services, to provide drugs specifically approved for HIV disease to certain eligible applicants. Also referred to as the "HDR program" or as the "program".~~

~~(o) — MEDICAID — The State Medicaid Program of the Tennessee Department of Health.~~

~~Authority: — T.C.A. §§ 4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.
Administrative History: — Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990.~~

~~1200-14-2-.02 PURPOSE AND ADMINISTRATION OF THE HIV DRUG REIMBURSEMENT (HDR) PROGRAM.~~

~~The purpose of the HDR program is to pay for the cost of certain life-sustaining and infection-preventing drugs for low-income Tennessee residents with HIV disease who have no other method of procuring the drug(s). The drugs covered by the state program shall be chosen from among those authorized in the federally-funded HDR program and must have FDA approval for specific use in HIV disease. Drugs currently approved under the federal program include AZT, aerosolized pentamidine and Alpha interferon. Additional drugs may be considered for the state program as they are authorized under the federal HDR program. The determining criteria for including an authorized drug in the state program shall include relative demand and cost of the drug, available funds and distribution requirements. The decision to add or delete a drug from the program shall be made jointly by the AIDS Program Director, the Medical Director, and the HDR program administrator. Funds shall be used to purchase drugs at the lowest possible cost under state contracts to fill valid prescriptions for recipients enrolled in the program. Departmental resources shall be utilized for storage, accountability and distribution.~~

~~All aspects of the recipient's use of the drug(s) including dosage, directions, temporary or permanent withdrawal, etc. shall be under the direction of the recipient's physician who jointly signs the program application.~~

~~Income eligibility will be determined based upon a client's income at 300% of the current year's Federal Poverty Level.~~

~~In addition to monthly income limitations, applicants must have less than \$8,000 in liquid resources, must not have third-party prescription coverage for the drug, and must not be authorized to receive Medicaid benefits.~~

~~The program shall develop and distribute applications and instructional forms. Current maximum income levels, specific drugs covered by the program and other guidelines for participation shall be published and made available to applicants, interested physicians, and other inquiring parties. The program shall require applicants and their attending physicians to complete and sign applications which state that they understand and meet all eligibility criteria for the program. In addition, the program shall incorporate procedures to provide drug inventory control from time of purchase to the filling of a legal prescription for an authorized program recipient. The program shall coordinate with Medicaid to ensure that persons shall not receive benefits from both programs simultaneously.~~

~~Authority: — T.C.A. §§ 4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.
Administrative History: — Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990. Amendment filed December 29, 1995; effective April 29, 1996.~~

~~*Example of monthly income level criteria for a single adult without dependents applying for *Retrovir* coverage under the program: If the current average out-of-pocket cost for a month's supply of *Retrovir* was \$800.00 and the current Federal Poverty Income Standard was \$480.00, then, the current maximum allowable monthly income for a program participant would be \$1280.00.~~

~~1200-14-2-.03 PROGRAM LIMITED TO AVAILABLE FUNDS.~~

~~The reimbursement for drugs by the HDR Program shall be limited by the availability of funds appropriated by the Tennessee General Assembly specifically for that purpose.~~

~~The approval of new applications shall cease if funding is not available to provide new recipients at least a six-month supply of drug(s). Applications meeting eligibility criteria but denied due to funding shortage shall be retained for reconsideration when funding becomes available. Priority for funding shall be given to recipients already in the program. Priority among pending applications shall be based upon the date received in the program office.~~

~~*Authority:* T.C.A. §§4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.~~

~~*Administrative History:* Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990.~~

~~1200-14-2-.04 ELIGIBILITY CRITERIA.~~

- ~~(1) To be deemed eligible for coverage by the HDR program a recipient must meet all of the following criteria:~~
 - ~~(a) meet the medical criteria established by generally accepted and proven treatment standards for HIV disease, including standards derived from published drug trials and recommendations of federal agencies;~~
 - ~~(b) have been prescribed the drug(s) by a physician licensed in Tennessee;~~
 - ~~(c) have a signed statement from the prescribing physician indicating the physician's intent to medically follow the applicant and monitor the intake and potential side effects of the drug(s);~~
 - ~~(d) declare that they are not receiving and are not authorized to receive Medicaid benefits;~~
 - ~~(e) meet the program's financial and resource criteria;~~
 - ~~(f) not be covered by any other source of third-party reimbursement for the prescribed drug(s);~~
 - ~~(g) submit a completed and signed HDR program application form.~~

~~*Authority:* T.C.A. §§4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.~~

~~*Administrative History:* Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990.~~

~~1200-14-2-.05 DEEMING OF INCOME AND RESOURCES.~~

- ~~(1) ADULTS: for the purpose of eligibility determination for an applicant 18 years of age or older, only the income and resources of the applicant and the applicant's legal spouse with whom the applicant resides shall be used in the HDR program eligibility determination~~
- ~~(2) MINORS: for the purpose of eligibility determination for an applicant under the age of 18, the income and resources of the applicant and the income and resources of the legal parent or parents with whom the applicant resides shall be used in the HDR program eligibility determination. Income and resources of stepparents and legal guardians shall not be used in the HDR program eligibility determination.~~

(Rule 1200-14-2-.05, continued)

~~*Authority:* T.C.A. §§4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.
Administrative History: Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990.~~

1200-14-2-.06 CERTIFICATION OF COVERAGE BY PROGRAM.

~~Upon approval of an application, the recipient shall be notified in writing of their certification to receive coverage by the HDR program. The recipient shall additionally be informed that the benefit coverage shall continue for a minimum of 6 months, or until the person gains Medicaid benefits, or until the end of the federal fiscal year during which the person was certified; whichever comes first. The applicant shall be further informed that assurance of coverage shall not extend beyond the current federal fiscal year.~~

~~*Authority:* T.C.A. §§4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.
Administrative History: Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990.~~

1200-14-2-.07 CONFIDENTIALITY OF RECORDS.

~~All applicant or recipient identifying information or records of the HDR program shall be considered confidential as required by the federal legislation authorizing funding assistance to the program. Such information or records shall not be disclosed by the program except for those purposes for which a signed release is provided by the person served. All correspondence containing the identity of program applicants or recipients shall be sealed and marked "CONFIDENTIAL".~~

~~*Authority:* T.C.A. §§4-5-204, 10-7-504(a)(1), 68-1-103, 68-1-106, 68-10-109, 68-10-113 and 68-10-114.
Administrative History: Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990.~~

1200-12-02-.01 Definitions

- (1) For the purpose of these regulations the terms used herein are defined as follows:
- (a) "ADAP" means the AIDS Drug Assistance Program, the federal earmark in the Ryan White Part B grant providing funding for HIV Clients' medications, which encompasses HDAP and IAP.
 - (b) "AIDS" means Acquired Immune Deficiency Syndrome or Acquired Immunodeficiency Syndrome.
 - (c) "Certification" means the determination that an applicant meets the eligibility criteria to receive assistance through the Ryan White Program.
 - (d) "Client" means a person enrolled in the Ryan White Program.
 - (e) "Department" means the Tennessee Department of Health.
 - (f) "FDA" means the U.S. Food and Drug Administration.
 - (g) "Formulary" means the HDAP Formulary, which lists the FDA approved medications provided by Tennessee's HDAP Program.
 - (h) "HDAP" means the HIV Drug Assistance Program, a program through which the Department provides Formulary medications to Clients.

- (i) "HIV" means Human Immunodeficiency Virus.
- (j) "IAP" means Insurance Assistance Program, a program through which the Department provides assistance paying health insurance premiums, co-payments, and/or deductibles for eligible Clients.
- (k) "Priority Group" means those eligible for temporary emergency access to HDAP or IAP services if there is a waiting list.
- (l) "Program Director" means the Department employee responsible for the overall management of grants and programs in the HIV/AIDS/STD Section of the Department.
- (m) "Provider" means a health care professional with prescriptive authority, licensed pursuant to Title 63 of the Tennessee Code.
- (n) "Ryan White Program" means the Departmental program that receives federal Ryan White Part B funding and provides medical services, medications, and support services to eligible individuals.
- (o) "TennCare" means Tennessee's State Medicaid Program.

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.

1200-14-02-.02 Purpose and Administration of ADAP Funds

(1) HDAP

Through HDAP, the Department shall:

- (a) Provide applications and instructional forms regarding eligibility criteria, the Formulary, and other guidelines for participation;
- (b) Determine which medications shall be included in the Formulary;
- (c) Purchase Formulary medications for Clients;
- (d) Contract licensed pharmacists to Provide Formulary medications to Clients pursuant to prescriptions by providers; and
- (e) Coordinate with TennCare to ensure that Clients do not receive benefits from both programs simultaneously.

(2) IAP

Through IAP, the Department shall:

- (a) Provide applications and instructional forms regarding eligibility criteria, the Formulary, and other guidelines for participation;
- (b) Provide assistance paying health insurance premiums, co-payments, and/or deductibles for eligible Clients.

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.

1200-14-02-.03 Eligibility Criteria

- (1) To qualify for Ryan White Program services, an applicant must submit a completed and signed Ryan White Program application including evidence that applicant meets the following eligibility requirements:
 - (a) Is a resident of Tennessee;
 - (b) Meets the generally accepted medical criteria for HIV disease;
 - (c) Has an annual income of less than 300% of the current year's federal poverty level;
 - (d) Has no more than \$8,000.00 in liquid assets; and
 - (e) For ADAP applicants, presents certification that applicant has no other source of third party reimbursement for prescription drugs.
- (2) For purposes of establishing income and assets the following shall apply:
 - (a) For applicants 18 years and older, only the income and assets of the applicant and the applicant's legal spouse with whom the applicant resides will be considered.
 - (b) For applicants less than 18 years of age, the income and assets of the applicant and the legal parent or parents with whom the applicant resides will be considered. Income and assets of step-parents and legal guardians shall not be considered.
- (3) In order to continue to receive any Ryan White Program services, a Client must submit the following every six (6) months:
 - (a) Confirmation that the Client continues to meet the eligibility criteria; and
 - (b) A completed and signed recertification application.

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, 68-10-109.

1200-14-02-.04 Program Limited to Available Funds

- (1) The availability of funds limits the number of Clients receiving ADAP services. The Department shall cease approval of applications if funding is insufficient to sustain additional recipients.
- (2) Current Clients shall have priority for funding.
- (3) Eligible applicants who are denied ADAP enrollment due to a funding shortage shall be placed on a waiting list managed by the Ryan White Program.
- (4) Individuals on the ADAP waiting list in one of the following Priority Groups shall be provided with temporary emergency ADAP services as follows:
 - (a) Pregnant women shall be eligible for ADAP services during pregnancy and up to 90 days post partum; and

- (b) Infants up to one year of age shall be eligible for ADAP services for up to 180 days of coverage.

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.

1200-14-02-.05 Certification of Coverage by Program

- (1) The Department will notify applicants whether certification of coverage has been awarded. Applicants for whom coverage is certified are not guaranteed ADAP services beyond the federal fiscal year of the current grant.

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.

1200-14-02-.06 Reconsideration of Denial

- (1) Applicants denied or removed from participation in HDAP or IAP may request reconsideration.

- (a) The applicant must request reconsideration in writing, directed to the Program Director, within twenty one (21) calendar days of denial or removal. The Program Director will issue a reconsidered decision in writing within fourteen (14) days of the request for reconsideration. The Program Director's review is limited to a determination of whether or not the applicant meets eligibility criteria. The decision of the Program Director is final.

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.

1200-14-2-.07 Confidentiality of Records.

All applicant or recipient identifying information or records of the ADAP program shall be considered confidential as required by the federal legislation authorizing funding assistance to the program. Such information or records shall not be disclosed by the program except for those purposes for which a signed release is provided by the person served. All correspondence containing the identity of program applicants or recipients shall be sealed and marked "CONFIDENTIAL".

Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-106, and 68-10-109.