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Sequence Number: 12-21-15  
Rule ID(s): 6091  
File Date: 12/23/15  
Effective Date: 3/22/16

## Proposed Rule(s) Filing Form

*Proposed rules are submitted pursuant to Tenn. Code Ann. §§ 4-5-202, 4-5-207, and 4-5-229 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 ninety (90) days of 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.*

*Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).*

<b>Agency/Board/Commission:</b>	Tennessee Department of Health
<b>Division:</b>	Division of Communicable and Environmental Disease and Emergency Preparedness, AIDS Program Division
<b>Contact Person:</b>	Mary Kennedy
<b>Address:</b>	710 James Robertson Parkway, 5th Floor, Nashville, TN 37243
<b>Zip:</b>	37234
<b>Phone:</b>	(615) 253-4878
<b>Email:</b>	<a href="mailto:mary.kennedy@tn.gov">mary.kennedy@tn.gov</a>

**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	Aids Drugs Assistance Program Rules
Rule Number	Rule Title
1200-14-02-.03	Eligibility Criteria
1200-14-02-.04	Program Limited to Available Funds

(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>)

Rule Chapter 1200-14-02  
Aids Drugs Assistance Program Rules

Amendments

Rule 1200-14-02-.03 Eligibility Criteria is amended by deleting paragraph (1) in its entirety including its subparagraphs and substituting instead the following language, so that as amended, the new paragraph (1) shall read:

- (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) An income level and total liquid assets that do not exceed the limits set by the Department and posted semiannually on its website; and
  - (d) For ADAP applicants, presents certification that applicant has no other source of third party reimbursement for prescription drugs.

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

Rule 1200-14-02-.04 Program Limited to Available Funds is amended by inserting new paragraph (5) which shall read:

- (5) The Department shall review available funding by March 31 and September 30 of each year, at which time it shall notify all current clients of the maximum income level and liquid assets for program eligibility. The Department will also post this information on its website.

Authority: T.C.A. §§ 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)
N/A					

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the (board/commission/other authority) on 12.10.15 (date as mm/dd/yyyy), 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 ninety (90) days of the filing of the proposed rule with the Secretary of State.

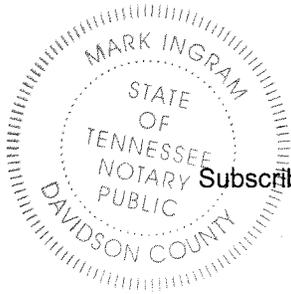
Date: 12.11.15

Signature: Mary Kennedy

Name of Officer: Mary Kennedy

Deputy General Counsel

Title of Officer: Department of Health



Subscribed and sworn to before me on: 12/11/15

Notary Public Signature: Mark Ingram

My commission expires on: 3/6/19

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.

Herbert H. Slatery III

Herbert H. Slatery III  
Attorney General and Reporter

12/23/2015

Date

**Department of State Use Only**

Filed with the Department of State on: 12/23/15

Effective on: 3/22/16

Tre Hargett

Tre Hargett  
Secretary of State

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SECRETARY OF STATE  
PUBLICATIONS

### **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.

- (1) **The extent to which the rule or rules may overlap, duplicate, or conflict with other federal, state, and local governmental rules.**

These rules do not overlap, duplicate, or conflict with other federal, state, or local governmental rules.

- (2) **Clarity, conciseness, and lack of ambiguity in the rule or rules.**

These rules exhibit clarity, conciseness, and lack of ambiguity.

- (3) **The establishment of flexible compliance and/or reporting requirements for small businesses.**

These rules do not affect compliance or reporting requirements for small businesses.

- (4) **The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.**

These rules do not affect schedules or reporting requirements for small businesses.

- (5) **The consolidation or simplification of compliance or reporting requirements for small businesses.**

These rules do not consolidate or simplify compliance or reporting requirements for small businesses.

- (6) **The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.**

These rules do not establish performance standards for small businesses.

- (7) **The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.**

These rules do not stifle entrepreneurial activity, curb innovation, or increase costs.

## STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

**Name of Board, Committee or Council:** Communicable and Environmental Disease and Emergency Preparedness

**Rulemaking hearing date:** N/A

- 1. Type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:**

HIV/Aids patients as well as health care providers including social service agencies working with HIV/AIDS patients will benefit from the proposed rule amendments.

- 2. Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:**

The proposed rule amendments will not affect reporting, recordkeeping or administrative costs.

- 3. Statement of the probable effect on impacted small businesses and consumers:**

The rule amendments will affect both consumers and small businesses as the rule amendments will lead to increased access to lifesaving medications, decreased emergency room visits and decreased hospital admissions.

- 4. Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:**

There are no less burdensome, less intrusive or less costly alternative methods of achieving the purpose or objectives of the rule amendments.

- 5. Comparison of the proposed rule with any federal or state counterparts:**

**Federal:** The rule amendments are consistent with 42 U.S.C. § 300ff.

**State:** None.

- 6. Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.**

N/A

## **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)

The proposed rule amendments should not have a financial 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 T.C.A. § 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;

Rule 1200-14-02-.03: The amendments to the rule are merging subparagraphs (b) and (c) by removing the currently-stated income level and total liquid assets limits and replacing them with provisions stating that the applicable limits will be set by the Department and posted on its website.

Rule 1200-14-02-.04: New paragraph (5) is being added to state how the Department will review funding and inform clients of their eligibility.

- (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;

42 U.S.C. § 300ff.

- (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;

HIV/Aids patients as well as health care providers including social service agencies working with HIV/AIDS patients will be affected by proposed rule amendments.

- (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;

These amendments should not result in any increase or decrease in state or local government revenues or expenditures.

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

Mary Kennedy, Deputy General Counsel, Department of Health.

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

Mary Kennedy, Deputy General Counsel, Department of Health.

- (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

Office of General Counsel, Department of Health, 710 James Robertson Parkway, 5th Floor, Nashville, TN, (615) 253-4878, Mary.Kennedy@tn.gov.

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

None.

**RULES  
OF  
THE DEPARTMENT OF HEALTH  
AIDS PROGRAM DIVISION**

**CHAPTER 1200-14-02  
AIDS DRUG ASSISTANCE PROGRAM RULES**

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**1200-14-02-.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.

(Rule 1200-14-02-.01, continued)

- (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. **Administrative History:** Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990. Repeal and new rule filed January 3, 2012; effective June 30, 2012.

#### 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. **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. Repeal and new rule filed January 3, 2012; effective June 30, 2012.

#### 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;~~

(Rule 1200-14-02-.03, continued)

- ~~(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.~~
- (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) An income level and total liquid assets that do not exceed the limits set by the Department and posted semiannually on its website; and
  - (d) 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. **Administrative History:** Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990. Repeal and new rule filed January 3, 2012; effective June 30, 2012.

#### **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

(Rule 1200-14-02-.03, continued)

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

(5) The Department shall review available funding by March 31 and September 30 of each year, at which time it shall notify all current clients of the maximum income level and liquid assets for program eligibility. The Department will also post this information on its website.

**Authority:** T.C.A. §§ 4-5-202, 68-1-103, 68-1-106, and 68-10-109. **Administrative History:** Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990. Repeal and new rule filed January 3, 2012; effective June 30, 2012.

#### **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. **Administrative History:** Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990. Repeal and new rule filed January 3, 2012; effective June 30, 2012.

#### **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. **Administrative History:** Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990. Repeal and new rule filed January 3, 2012; effective June 30, 2012.

#### **1200-14-02-.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. **Administrative History:** Original rule filed March 31, 1988; effective May 15, 1988. Amendment filed January 26, 1990; effective March 12, 1990. Repeal and new rule filed January 3, 2012; effective June 30, 2012.