

NOTICE OF PROPOSED EXPEDITED RULEMAKING
TITLE 9. HEALTH SERVICES
CHAPTER 6. DEPARTMENT OF HEALTH SERVICES
COMMUNICABLE DISEASES AND INFESTATIONS
ARTICLE 4. AIDS DRUG ASSISTANCE PROGRAM (ADAP)

PREAMBLE

1. Permission to initiate this rulemaking was granted under A.R.S. § 41-1039(A) by the governor on:

August 19, 2024

<u>2. Article, Part or Sections Affected (as applicable)</u>	<u>Rulemaking Action</u>
---	---------------------------------

R9-6-403	Amend
----------	-------

R9-6-404	Amend
----------	-------

3. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statutes: A.R.S. §§ 36-132(A)(1), 36-136(G)

Implementing statutes: A.R.S. § 36-136(I)

4. Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 30 A.A.R. XXXXX, August 13, 2024 [Added by Register editor]

5. The agency's contact person who can answer questions about the rulemaking:

Name: Ricardo Fernandez, Ryan White Part B/ADAP Program Director

Address: Arizona Department of Health Services

Public Health Preparedness

150 N. 18th Ave., Suite 110

Phoenix, AZ 85007

Telephone: (602) 364-3854

Fax: (602) 542-1155

E-mail: Ricardo.Fernandez @azdhs.gov

or

Name: Stacie Gravito, Office Chief

Address: Arizona Department of Health Services

Office of Administrative Counsel and Rules
150 N. 18th Ave., Suite 200
Phoenix, AZ 85007

Telephone: (602) 542-1020

Fax: (602) 364-1150

E-mail: Stacie.Gravito@azdhs.gov

6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

Arizona Revised Statutes (A.R.S.) § 36-136(I)(1) requires the Arizona Department of Health Services (Department) to make rules defining and prescribing “reasonably necessary measures for detecting, reporting, preventing, and controlling communicable and preventable diseases.” The AIDS Drug Assistance Program (ADAP) helps individuals with HIV infection to obtain necessary prescription drugs to prevent the occurrence of, or to alleviate, disability from HIV-related diseases, including AIDS, and to reduce the spread of the disease. The Department has adopted rules for ADAP in 9 A.A.C. 6, Article 4. As specified in a recent five-year-review report for the rules in 9 A.A.C. 6, Article 4, the Department identified a couple of minor issues that needed to be addressed to improve the effectiveness of the rules and reduce the administrative burden. After obtaining approval for the rulemaking according to A.R.S. § 41-1039(A), the Department is revising the rules to address the identified issues. The proposed amendments are consistent with the purpose for A.R.S. § 41-1027 in that this rulemaking does not increase the cost of regulatory compliance, does not increase a fee, or reduce a procedural right of regulated persons. In addition, the rulemaking implements, without material change, a course of action that was proposed in a five-year review report and reduces steps, procedures, or processes and amends rules that are outdated and unnecessary, while protecting the health and safety of patients and the general public.

7. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review or rely on any study for this rulemaking.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. A statement that the agency is exempt from the requirements under A.R.S. § 41-1055(G) to obtain and file a preliminary summary of the economic, small business, and consumer impact under A.R.S. § 41-1055(D)(2):

Under A.R.S. § 41-1055(D)(2), the Department is not required to provide an economic, small business, and consumer impact statement.

10. Where, when, and how a person may provide written comment to the agency on the proposed expedited rule under A.R.S. § 41-1027(C):

Close of record: Monday, October 14, 2024, 4:00 p.m.

A person may submit written comments on the proposed expedited rules no later than the close of record to either of the individuals listed in item 5.

11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

Not applicable; the rules do not require the issuance of a permit or license.

b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

ADAP is mostly funded through federal funds under the Ryan White Comprehensive AIDS Resources Emergency Act (Ryan White CARE Act), Pub. L. 101-381, 104 Stat. 576, enacted August 18, 1990, and follows requirements of the federal funding agency. The rules also impose the same requirements on participants as the applicable provisions of Medicare Part D (*e.g.* 20 CFR Part 418, Subpart D) for acquiring prescription drugs through plans under contract to Medicare. The rules are not more stringent than these federal requirements but are based on a state statute, rather than federal regulation.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:

No business competitiveness analysis was received by the Department.

12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:

Not applicable

13. The full text of the rules follows:

TITLE 9. HEALTH SERVICES
CHAPTER 6. DEPARTMENT OF HEALTH SERVICES
COMMUNICABLE DISEASES AND INFESTATIONS
ARTICLE 4. AIDS DRUG ASSISTANCE PROGRAM (ADAP)

Section

- R9-6-403. Eligibility Requirements
- R9-6-404. Initial Application Process

ARTICLE 4. AIDS DRUG ASSISTANCE PROGRAM (ADAP)

R9-6-403. Eligibility Requirements

An individual is eligible to enroll in ADAP if the individual:

1. Has a diagnosis of HIV infection from a physician, registered nurse practitioner, or physician assistant;
2. Is a resident of Arizona, as established by documentation that complies with R9-6-404(A)(8);
3. Has an annual household income that is less than or equal to 400% of the poverty level; and
4. Satisfies one of the following:
 - a. Has no health insurance coverage and has not opted out of health insurance coverage to which the individual is eligible;
 - b. Has inadequate health insurance coverage, which may include Medicare or an AHCCCS health plan, limiting the ability of the individual to obtain drugs, such as health insurance coverage that:
 - i. Does not cover drugs,
 - ii. Does not include on its formulary at least one of the drugs prescribed for the individual, or
 - iii. Requires the use of specific pharmacies or higher co-payments for obtaining a drug;
 - c. Has health insurance that is unaffordable because premiums exceed 9.5% of the applicant's annual household income;
 - d. Is an American Indian or Alaska Native who:
 - i. Is eligible for, but chooses not to use, the Indian Health Service or a clinic operated by a sovereign tribal nation to receive drugs; and
 - ii. Either has no other health insurance coverage or has other health insurance coverage that is inadequate or unaffordable, as described in subsections (4)(b) and (c); or
 - e. Is an individual who has served in the United States Armed Forces and who:
 - i. Is eligible for, but chooses not to use, Veterans Health Administration benefits to receive drugs; and
 - ii. Either has no other health insurance coverage or has other health insurance coverage that is inadequate or unaffordable, as described in

subsections (4)(b) and (c).

R9-6-404. Initial Application Process

- A.** An applicant for initial enrollment in ADAP or the applicant's representative shall submit to the Department the following application packet:
1. An application in a Department-provided format, completed by the applicant or the applicant's representative, containing:
 - a. The applicant's name, date of birth, and gender;
 - b. Except as provided in subsection (A)(1)(c), the applicant's residential address and mailing address;
 - c. If the applicant is in non-permanent housing, the address of a person that has agreed to receive written communications for the applicant;
 - d. If applicable, the address in Arizona to which the applicant would want drugs to be shipped;
 - e. If applicable, the name of the applicant's representative and the mailing address of the applicant's representative, if different from the applicant's mailing address;
 - f. Either:
 - i. The telephone number of the applicant or a person that has agreed to receive telephone communications for the applicant, or
 - ii. An email address for the applicant;
 - g. The number of individuals in the applicant's household that can be claimed on the applicant's income taxes and the names and ages of the individuals;
 - h. The names of individuals, other than the persons specified in subsection (A)(1)(s)(v), with whom the applicant authorizes the Department to speak about the applicant's enrollment in ADAP;
 - i. The applicant's annual household income;
 - j. The applicant's race and ethnicity;
 - k. Whether the applicant or an adult in the applicant's household:
 - i. Is employed;
 - ii. Is self-employed;
 - iii. Is receiving regular monetary payments from a source not specified in subsection (A)(1)(k)(i) or (ii) and, if so, an identification of the source of the monetary payments; or
 - iv. Is using a source not specified in subsections (A)(1)(k)(i) through (iii) or

- savings to assist the applicant in obtaining food, water, housing, or clothing for the applicant and if so, an identification of the source;
- l. Whether the applicant is receiving health insurance coverage from AHCCCS and:
 - i. If so, the name of the AHCCCS health plan and the date enrolled; and
 - ii. If the applicant's eligibility determination for AHCCCS is pending, the date the application for AHCCCS was submitted;
 - m. Whether the applicant is eligible for Medicare health insurance coverage and, if not, the date on which the applicant will be eligible for Medicare health insurance coverage;
 - n. If the applicant is eligible for Medicare health insurance coverage, whether:
 - i. The applicant, or the applicant's representative has applied for a low-income subsidy for the applicant and, if so, the date of the application for the low-income subsidy; and
 - ii. Either:
 - (1) The applicant or the applicant's representative has applied for a Medicare drug plan for the applicant and, if so, the date of the application for the Medicare drug plan; or
 - (2) The applicant is enrolled in a Medicare drug plan;
 - o. Whether the applicant or the applicant's spouse has or is eligible to enroll in health insurance coverage other than AHCCCS or Medicare that would pay for drugs on the ADAP formulary;
 - p. If the applicant or the applicant's spouse is eligible to enroll in health insurance coverage other than Medicare that would pay for drugs on the ADAP formulary but enrollment is closed, the date the next health insurance enrollment period begins;
 - q. Whether the applicant is eligible to receive benefits from:
 - i. The Indian Health Service or a clinic operated by a sovereign tribal nation, or
 - ii. The Veterans Health Administration;
 - r. Whether the applicant is living in non-permanent housing or is in another situation in which the applicant's financial records to verify annual household income, as specified in subsection (A)(6), are not available to the applicant;
 - s. A statement by the applicant or the applicant's representative confirming that the

applicant or the applicant's representative:

- i. Understands that, if the annual household income of the applicant is at an amount that may make the applicant eligible for enrollment in AHCCCS, the applicant or the applicant's representative is required to submit to the Department documentation stating the applicant's status for enrollment in AHCCCS before the end of the month after the month in which the applicant applied for ADAP, if not provided to the Department with the application;
- ii. Except as provided in R9-6-405(E), if the applicant is eligible for Medicare, understands that the applicant or the applicant's representative is required to submit to the Department proof of enrollment in a Medicare drug plan before the end of the month after the month in which the applicant applied for ADAP, if not provided to the Department with the application;
- iii. Except as provided in R9-6-405(E), if the applicant is eligible for Medicare and the annual household income of the applicant is less than 175% of the poverty level, understands that the applicant or the applicant's representative is required to submit to Department documentation of the applicant's status for a low-income subsidy before the end of the month after the month in which the applicant applied for ADAP, if not provided to the Department with the application;
- iv. Except as provided in R9-6-405(E), if the applicant or the applicant's spouse has or is eligible for health insurance coverage other than AHCCCS or Medicare, understands that the applicant or the applicant's representative is required to submit to the Department information about the health insurance coverage to enable the Department to determine if the health insurance coverage is inadequate, according to R9-6-403(4)(b), or unaffordable, according to R9-6-403(4)(c), before the end of the month after the month in which the applicant applied for ADAP, if not provided to the Department with the application;
- v. Grants permission to the Department to discuss the information provided to the Department under subsection (A) with:
 - (1) AHCCCS, for the purpose of determining AHCCCS eligibility;
 - (2) Medicare and the Social Security Administration, for the purpose

- of determining eligibility for a low-income subsidy and enrollment in a Medicare drug plan;
 - (3) The applicant's HIV-care provider or designee;
 - (4) The contract pharmacy or a pharmacy at which the applicant or the applicant's representative may request a drug through ADAP, to assist with drug distribution;
 - (5) Other providers of services for persons living with HIV that are funded through Ryan White;
 - (6) Other providers of HIV-related services, as applicable to the applicant; and
 - (7) Any other entity as necessary to establish eligibility for enrollment in ADAP or assist with drug distribution to the applicant or payment of prescription co-payment costs;
 - vi. Understands that the applicant or the applicant's representative is required to submit to the Department proof of the applicant's annual household income as part of the application; and
 - vii. Understands that the applicant or the applicant's representative is required to notify the Department of changes specified in R9-6-406(A);
 - t. A statement by the applicant or the applicant's representative attesting that:
 - i. To the best of the knowledge and belief of the applicant or the applicant's representative, the information and documents provided to the Department in the application packet is accurate and complete;
 - ii. The applicant meets the eligibility criteria specified in R9-6-403; and
 - iii. The applicant or applicant's representative understands that eligibility does not guarantee that the Department will be able to provide drugs and understands that an individual's enrollment in ADAP may be terminated as specified in R9-6-408; and
 - u. The dated signature of the applicant or the applicant's representative;
2. The information specified in subsection (B), completed by the applicant's HIV-care provider in a Department-provided format;
 3. If the annual household income of the applicant is an amount that may make the applicant eligible for enrollment in AHCCCS, a copy of documentation from AHCCCS, dated within 60 calendar days before the date of application, stating the status of the applicant's eligibility for enrollment in AHCCCS;

4. If the applicant is eligible for Medicare, a copy of valid documentation stating:
 - a. The applicant's enrollment in a Medicare drug plan; and
 - b. If the applicant's annual household income is at or below 175% of the poverty level, the status of the applicant's eligibility for a low-income subsidy;
5. If the applicant or the applicant's spouse has or is eligible for health insurance coverage other than AHCCCS or Medicare:
 - a. Information about the health insurance coverage to enable the Department to determine whether the health insurance coverage is inadequate, according to R9-6-403(4)(b), or unaffordable, according to R9-6-403(4)(c); and
 - b. If the applicant has other health insurance coverage, documentation confirming the health insurance coverage;
6. Except as provided in subsection (C), proof of the applicant's annual household income, including the following items as applicable to the applicant's household:
 - a. An income tax return submitted by the applicant for the previous tax year to the U.S. Internal Revenue Service or the Arizona Department of Revenue;
 - b. If an income tax return in subsection (A)(6)(a) is not available, for each job held by an adult in the household:
 - i. Paycheck stubs from within 60 calendar days before the date of application, or
 - ii. A statement from the employer listing gross wages for the 30 calendar days before the date of application;
 - c. If an income tax return in subsection (A)(6)(a) is not available, from each self-employed adult in the household, documentation of the net income from self-employment, such as:
 - i. The Internal Revenue Service Forms 1099 prepared for the previous tax year for the self-employed adult in the household;
 - ii. A profit and loss statement for the self-employed adult's business, covering a period ending no earlier than three months before the date of application; or
 - iii. Bank statements from the self-employed adult's checking and savings accounts, covering a period ending no earlier than three months before the date of application; and
 - d. Documentation showing the amount and source of any regular monetary payments received by an adult in the household from sources other than those

specified in subsection (A)(6)(a) through subsection (A)(6)(c);

7. If the applicant or the applicant's representative has stated according to subsection ~~(A)(1)(k)(v)~~ (A)(1)(k)(iv) that the applicant has no source of regular monetary payments and is unable to provide any of the documentation specified in subsection (A)(6), the following, in a Department-provided format, completed and signed within 30 calendar days before the date of application, containing:
 - a. Information completed by the applicant or the applicant's representative stating whether:
 - i. An adult in the applicant's household receives money from intermittent work performed by the adult in the household for which no paycheck stub is received and, if so, the average monthly earnings, and the adult's occupation;
 - ii. The applicant is living in non-permanent housing;
 - iii. The applicant is receiving assistance from another individual; and
 - iv. The applicant has another source of assistance for obtaining food, water, housing, and clothing, and, if so, an identification of the source;
 - b. A statement by the applicant or the applicant's representative attesting that, to the best of the knowledge and belief of the applicant or the applicant's representative, the information submitted under subsection (A)(7)(a) is accurate and complete; and
 - c. The dated signature of the applicant or the applicant's representative; and
8. Proof that the applicant is a resident of Arizona that includes:
 - a. One of the following that shows the Arizona residential address specified according to subsection (A)(1)(b) and the name of the applicant or an adult in the applicant's household:
 - i. Documentation issued by a governmental entity related to the applicant's eligibility for benefits, dated within 60 calendar days before the date of application;
 - ii. Valid documentation from the Social Security Administration or the Department of Veterans Affairs related to the applicant's eligibility for benefits;
 - iii. A property tax statement for the most recent tax year issued by a governmental entity;
 - iv. A homeowners' association assessment or fee statement, dated within 60

- calendar days before the date of application;
- v. A valid lease agreement;
- vi. A mortgage statement for the most recent tax year;
- vii. A letter issued by an entity providing non-permanent housing to the applicant, dated within 30 calendar days before the date of application;
- viii. Any document or mail dated within 60 calendar days before the date of application and received by the applicant, including a utility bill, check stub, or statement of direct deposit issued by an employer, a bank or credit union statement, a credit card statement, a mobile telephone company billing statement, a billing statement or receipt from an HIV-care provider's office, or a document from an insurance company;
- ix. A non-expired Arizona driver license issued by the Arizona Department of Transportation's Motor Vehicle Division within the previous 12 months;
- x. A non-expired Arizona vehicle registration issued by the Arizona Department of Transportation's Motor Vehicle Division within the previous 12 months;
- xi. A non-expired Arizona identification card issued by the Arizona Department of Transportation's Motor Vehicle Division within the previous 12 months; or
- xii. A tribal enrollment card or other type of tribal identification; or
- b. If the applicant is unable to produce documentation that satisfies subsection (A)(8)(a), one of the following that includes the name of the applicant or an adult in the applicant's household and is dated within 30 calendar days before the date of application:
 - i. A written statement issued by the applicant's case manager verifying that the applicant is living in non-permanent housing and a resident of Arizona;
 - ii. A written statement issued by the applicant's case manager indicating that the case manager has conducted a home visit with the applicant at the Arizona residential address specified according to subsection (A)(1)(b); or
 - iii. A written statement issued by the applicant's HIV-care provider, verifying that the applicant is a resident of Arizona; ~~and~~

9. ~~If the applicant or the applicant's representative has stated according to subsection (A)(7) that the applicant receives assistance from another individual, a letter from the individual to support the statement of the applicant or the applicant's representative.~~
- B.** The HIV-care provider of an applicant for initial enrollment in ADAP shall provide:
1. The following information for the applicant in a Department-provided format:
 - a. The applicant's name;
 - b. The HIV-care provider's name, business address, telephone number, email address, fax number, and professional license number;
 - c. A statement that the applicant has been diagnosed with HIV infection;
 - d. A list of each drug prescribed for the applicant by the HIV-care provider;
 - e. A statement by the HIV-care provider attesting that, to the best of the HIV-care provider's knowledge and belief, the information provided to the Department as specified in subsection (B) is accurate and complete; and
 - f. The dated signature of the HIV-care provider;
 2. Documentation confirming HIV-infection of the applicant; and
 3. A copy of the most recent laboratory report of a test for viral load and, if available, CD4-T-lymphocyte count conducted for the applicant.
- C.** If an applicant or the applicant's representative stated in subsection (A)(1)(r) that the applicant is in a situation in which the applicant's financial records to verify annual household income, as required in subsection (A)(6), are not available to the applicant, the applicant or the applicant's representative may submit to the Department a statement describing the applicant's situation and provide whatever documentation the applicant has available to demonstrate the applicant's annual household income.